Exhibit E

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
Master File No. 2:12-MD-02327

THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN THE WAVE 1 OF MDL 200:

WENDY HAGANS,
Plaintiff,
v.
Case No: 2:12-cv-00783
ETHICON, INC., ET AL.,
Defendant(s).
_____/

DEPOSITION OF
BRIAN SCHWARTZ, M.D.

Taken in re: TVT-O Litigation

DATE TAKEN: March 25, 2016
TIME: 9:15 a.m.
PLACE: 5237 Summerlin Commons Blvd.
Fort Myers, Florida

Examination of the witness taken before:
Elizabeth M. Brooks, RPR, FPR
2650 Airport Road South
Naples, FL 34112

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WHEREUPON,

BRIAN SCHWARTZ, M.D.,

having been duly sworn to tell the truth, testified upon his oath as follows:

DIRECT EXAMINATION

BY MS. O'DELL:

Q Good morning, Dr. Schwartz.

A Good morning.

Q My name is Leigh O'Dell. We met a few minutes ago off the record. I'm here to ask you some questions about your TVT-O general report for the Ethicon Wave cases. And so you provided a number of notebooks to me today, and I'm assuming that is in response to the notice of deposition.

Let me show it to you. Exhibit 1.

(Exhibit 1 marked for identification.)

BY MS. O'DELL:

Q Have you seen that document before?

A Yes.

Q And if you'll turn, Dr. Schwartz, to Exhibit A of the notice.

A Okay.

Q Is there anything in your possession that relates to your work in this case that you have not brought with you to the deposition?

A No.

Q Okay. And is there anything that you have in your possession that your lawyer has instructed you not to bring?

A No.

Q You brought a number of notebooks, and let me just ask for a general understanding of how you prepared your opinions in this case.

Did you primarily review printed materials or did you review materials electronically as well?

A I've reviewed both.

Q In other words, did you review the materials electronically and then Ethicon counsel provided you with hard copies, or were you provided hard copies initially and you reviewed them upon receipt?

A Both. Actually, both ways. Some I received hard copies and reviewed them, and some I received electronically and reviewed them and then got the hard copies.

Q Let me do a few more housekeeping matters and I'll return to that.

Let me show you what I've marked as Exhibit 2 and ask you to identify that for the record.

(Exhibit 2 marked for identification.)

THE WITNESS: This appears to be my general

report for TVT-O.

(Exhibit 3 marked for identification.)

BY MS. O'DELL:

Q And would you identify Exhibit 3, please?

A This is my up-to-date CV.

Q I'm handing you Exhibit 4, and please identify that for the record.

(Exhibit 4 marked for identification.)

THE WITNESS: I believe this is the reliance list that was provided to me.

BY MS. O'DELL:

Q Did you review all of the materials that are listed on Exhibit 4?

A I have reviewed most, at least in a cursory fashion.

Q If you'll turn to Page 2, you'll see that that starts a very lengthy list of medical literature.

Who identified these publications --

A Page 2?

Q -- for you to consider in rendering your opinion?

A My attorney, Mr. Koopmann.

Q Are there any articles that you identified independently of Ethicon counsel and asked that they be added to this list?

A I did forward some articles to Mr. Koopmann. I don't know if they have been added to the list or not.

Q Do you recall either the name or the first author of the articles?

A I do not.

Q What product did they relate to?

A They related to generalized female incontinence surgery.

Q Were they recently published articles or were --

A Recently published articles.

Q Okay. And in regard to their content, did they address a specific type of product?

A No, they did not.

Q And what were -- what was the subject of the articles?

A The effectiveness of various female incontinence surgeries.

Q Did they include efficacy rates of the TVT-O?

A No.

Q Did any of those articles address the efficacy of the TVT-Secur or another mini-sling?

A No.

Q Approximately how many articles did you forward to your attorney?

A Two or three.
Q Did you perform any PubMed searches or any other type of searches for literature?
A I did not do any generalized searches, no.
Q If you'll turn to what appears to be about the last five or six pages of your reliance list, Exhibit 4, you'll see a list of production materials. I think you may have gone too far in the exhibit. The title at the top is Production Materials.
A Yes.
Q Are those materials or does this begin a list of materials that you were provided by Ethicon counsel of internal documents?
A Not all.
Q Did you add any of those items to your list or were they all added by Ethicon counsel?
A They were all added by Ethicon counsel.
Q Okay. Are those materials printed in one of these binders?
A Some of those materials will be in the binders. Should be labeled Company Documents.
Q I see this. I think the index is entitled TVT Company Documents.
A Yes.
Q I'm going to mark the notebook as Exhibit 5.

MR. KOOPMANN: Just for the record, the index is labeled TVT-O Company Documents.

(Exhibit 5 marked for identification.)

BY MS. O'DELL:

Q All right. I'm going to mark the binder as Exhibit 5, and it is various TVT-O company documents.

Who prepared this notebook?

A Ethicon counsel.

Q Did you review these materials?

A Yes, I did.

Q Did you review any company documents, with the exception of the IFUs, which I see here in another binder, for the TVT-O? Did you review any company documents electronically?

A Not that I recall.

Q So would it be fair to say that outside of the documents that are marked in Exhibit 5 and the IFUs that are in another binder, but I won't mark, to take pity on our court reporter since we all have copies of those, but other than those documents within the binders, is that the whole universe of company documents that you relied on in rendering your opinions in relation to the TVT-O?

A Yes.

Q And so, to the degree there are other company

documents that are listed in the Materials Reviewed list marked as Exhibit 4, those are not documents that you've relied on in rendering your opinions, correct?

MR. KOOPMANN: Objection. Form.

Go ahead.

THE WITNESS: Correct.

BY MS. O'DELL:

Q Who hired you to be involved in the Ethicon litigation?

A I was contacted towards the end of last year by Mr. Koopmann.

Q And did you know Mr. Koopmann prior to him contacting you?

A No.

Q How did he identify you as a potential expert?

MR. KOOPMANN: Objection. Foundation.

THE WITNESS: Apparently my name was in a list of names that was forwarded to him of TVT users.

BY MS. O'DELL:

Q You mean TVT-O users?

A Yes. The Ethicon product users.

Q Okay. And so is it your understanding that it was an Ethicon employee that forwarded a list to Ethicon counsel of TVT-O users?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I honestly do not have an answer to that.

BY MS. O'DELL:

Q Prior to your involvement in the Ethicon transvaginal mesh litigation, have you been an expert witness in other cases?

A Never.

Q And would that be true of product liability cases as well as med mal cases, or any other type cases?

A Correct.

Q Have you done any expert consulting for litigation, other than providing testimony?

A Never.

Q Have you been deposed before?

A Yes.

Q How many times, if you recall?

A For any reason?

Q For any purpose, yes.

A Half a dozen.

Q And in those particular circumstances, were those involved -- involving your professional work as a physician?

A Yes. They were involving -- most of them. I think one was for an auto accident my wife had. The rest were for patients who were involved in some type of

litigation. And there were some that just involved me.

Q Okay. And were those that involved you directly cases involving medical malpractice claims?

A Yes.

Q And how many cases involved medical malpractice?

A Three.

Q Okay. And if you'll start, just go through the list of three, if you don't mind, sir.

What were the -- very short summary of the allegations and then what was the outcome of the case.

A The first was when I was a surgery intern in 1990. The allegation was misdiagnosis of appendicitis. That was settled by the hospital.

The second was in the late nineties. I was covering for one of my partners, provided a patient with some antianxiety medication. The next day he was found in respiratory arrest, and that's number two, and that case was settled.

And the third is a high-risk patient of mine who, while in the hospital postoperatively, appeared to have cardiac arrest, and that was settled as well.

Q I'm going to mark a group of papers that Ethicon counsel has provided to me that appear to be your engagement letter in these cases, as well as

invoices.

(Exhibit 6 marked for identification.)

BY MS. O'DELL:

Q Let me just show you this and see if I've identified those correctly.

A Yes.

Q Okay. And since we only have one copy, if we can share. I'll ask you a few questions. If you need to see these, please just ask me.

A Sure.

Q It appears based on Page 1 of Exhibit 6 that you were engaged to serve as an expert in these cases on September the 1st?

A Yes.

Q And the first bill or invoice documenting work that I see has an entry for 12/4, or December 4.

Did you perform any work or do any preparation of your opinions between September 1st and December the 4th?

A Not that I recall.

Q And I have, you know, three general bills, one for December, one for January, one for February, that have all been made a part of this exhibit. And there is no delineation of whether the work was for a general report you prepared, individual case report. So let me

just ask you.

Are all of these invoices related to your TVT-O work?

A They are all related to any of the Ethicon work, so that would include the TVT-O, the TVT-Secur and the case work.

Q Okay. And you are serving as a case-specific expert in the Hagans case, and I'm aware of one other case, that I cannot recall the name of the case.

Are there any other cases besides those two that you are serving as a case-specific expert?

A No.

Q And, totaling these bills, Dr. Schwartz, it appears that you have spent approximately 67.5 hours, if my math is correct, on your work in these matters up until February the 28th.

What percentage of those hours, approximately, would be spent on the TVT-O general opinions?

A 70 percent.

Q Okay.

A As an estimate.

Q Fair enough.

And then how many hours, approximately, or what percentage of the hours would have been spent in preparing your TVT-Secur report?

A The other 30.
Q Okay. And that is 100 percent.
So what portion of your time was devoted to rendering your opinions in the case, the case specific?
A About -- I would estimate about 30 percent of each, so 30 percent of the 70 percent for the TVT-O, and 30 percent of the TVT-Secur for the case specific.
Q Okay. How many hours have you spent since February 28th on your work in relation to the overall Ethicon litigation?
A I would estimate around between 25 and 30 additional hours.
Q And what did you do during those 30 hours?
A I'm going to need you to be more specific.
Q Okay. Well, you wrote your report and you ostensibly -- let me start again.
From December to February the 28th, I'm assuming, you reviewed materials, you met with your lawyer, you wrote reports, and so that's up until February the 28th.
Since that time have you written any supplemental reports?
A No.
Q Have you reviewed new materials? In other words, how have you -- what did you do in the 25 to 30

hours that you've spent since February 28th? I'm just asking you, what kind of work did you do?

A Re-reviewing the materials.

Q How many hours did you spend -- let me back up.

Did you meet with counsel prior to your deposition?

A Yes.

Q When?

A This morning and last evening.

Q How many hours did you spend meeting with Mr. Koopmann?

A Three and a half.

Q Did you have any telephone conferences?

A We did.

Q And when approximately did that conference occur?

A Last evening.

Q Okay. So you talked to him by phone yesterday, or did you meet with him as well?

A We had a telephone conference with a third party by phone.

Q Okay. Who was the third party?

A I don't -- Helen Catherine.

Q Okay.

A That's all I know.
Q That's enough. I know of a Helen Catherine.
And I presume you talked about the Hagans case?
MR. KOOPMANN: Objection. I mean, you can't inquire into the communications between counsel and the witness unless it relates to information we provided him or compensation.
MS. O'DELL: I can ask. You are free to object.
MR. KOOPMANN: Objection.
And I'm going to instruct you not to answer, regarding the substance of our conversation, that question.
BY MS. O'DELL:
Q Let me ask this question.
Dr. Schwartz, in rendering your opinions in regard to Ethicon's TVT-O product, were you asked to make any assumptions in reaching your opinions? In other words, were you given facts or data to assume and base your opinions on those?
A If I understand the question correctly, I was asked to make my own assumptions based on the facts and data that were provided.
Q Okay. Let me ask you some questions about

your clinical practice.

What percentage of your current patient population is female?

A 30 percent.

Q And of those, the 30 percent, how many of those patients approximately would you be treating for stress urinary incontinence?

A My estimate would be 20 percent of that 30 percent.

Q I read in your report where you have performed approximately 600 sling procedures of some type or another?

A At least.

Q In your current practice how often on a monthly basis would you perform surgery for the treatment of SUI?

A Currently?

Q Yes.

A How many surgeries do I perform?

Q No. I asked you how many surgeries you would perform in females for the treatment of SUI on a monthly basis.

A Six. There has been a significant decline over the last couple of years.

Q In what?

A In my population of incontinence patients. One of the reasons had to do with our -- my practice voting to limit our practice to one hospital. Unfortunately that hospital does not include gynecologists, so referral patterns changed dramatically.

And, secondly, with all of the incontinence litigation, there has just been a dramatic change.

Q Are you currently using transvaginal mesh in the treatment of stress urinary incontinence?

A I am.

Q And what product are you using presently?

A I utilize the TVT-O and the TVT-Abbrevo.

Q You write in your report -- I'm looking on Page 2. Just a quick question.

You state that you performed Burch procedures in your residency?

A And in practice.

Q Do you presently perform the Burch procedure?

A I would perform the Burch procedure if there was an appropriate situation, but I have not performed a Burch procedure in several years.

Q Are you trained to perform Burch procedures laparoscopically? And it's not a trick question. I'm just asking, when you were trained, were you trained to

do them through an open abdominal incision?

A In my residency we did not. But as a practicing urologist I did help assist my partners with those procedures. So yes, I did perform them as a practicing urologist.

Q And those procedures were performed with an abdominal incision, correct?

A The laparoscopic Burch procedure? Yes. Through small abdominal incisions.

Q I think I misunderstood what you are saying.

You are saying you had performed laparoscopic Burches with your partners?

A Correct.

Q But you have not -- you didn't go through resident training using the laparoscopic approach to a Burch?

A Correct.

Q You state you have performed 600 sling procedures and several hundred TVT-Os, I've read in your TVT-O general report. In your TVT-Secur general report it says several hundred.

Would you give me a very big sort of estimate, of those 600 procedures, what percentage would be TVT-O?

A My comments in terms of the number were 300 TVT-O, 300 TVT-Secur, and I did not include the other

types of slings that I have done in my career. Pubovaginal slings, Monarc sling.

Q Right. You write on Page 2, "These include retropubic TVT, transobturator TVT-O, transobturator slings using the out-to-in method" -- which I'm assuming is the Monarc -- "the TVT-Abbrevo and mini-slings, including the TVT-Secur." I'm reading from Page 2 of Exhibit 2.

"I have performed over 600 of those procedures."

And so, of all of those types of sling procedures, is the total that you performed 600?

A That is the minimum, yes. I have performed more than 600.

Q Okay.

A I just rounded down to the closest number.

Q And if I understand your testimony, you've performed 300 TVT-O, 300 TVT-Securs, so that's 600?

A Yes.

Q Approximately how many TVT procedures have you performed?

A Ten.

Q And how many Abbrevo?

A Thirty.

Q How many Monarc?

A I'm relying on more than 15 years ago, so I'm giving you my best estimates.

I would say, for Monarc, 30.

Q If you'll turn to Page 6 of your report, Dr. Schwartz, middle of the page, you write, "All continence surgeries have similar risk, including bleeding, infection, persistent or recurrent SUI, voiding dysfunction, including overactive bladder symptoms and urinary retention, chronic pain, dyspareunia, injury to the vagina, urethra, bladder," et cetera.

What's your basis for that statement?

A A combination of my experience, texts, and the medical literature.

Q Do you keep a log of the surgical procedures that you perform?

A I used to.

Q When did you stop?

A Probably ten years ago.

Q So you presently do not keep a log of the patients and the type of procedures that you perform?

A I do not keep a log.

Q Have you performed a surgical revision or excision of an SUI sling?

A Yes.

Q Approximately how many?
A Thirty.
Q Have you revised a TVT-O sling?
MR. KOOPMANN: Objection. Form.
MS. O'DELL: What's the objection?
MR. KOOPMANN: Just, I think it's vague, "revised." That can mean a lot of things.
MS. O'DELL: I'm happy to restate that. Let me be more clear.
BY MS. O'DELL:
Q Have you done a surgical procedure to remove mesh from a TVT-O sling?
A Of those, that estimated group of 30, I cannot recall which -- how many of each different types of slings, because a majority of those patients were not implanted by myself, but I am fairly confident that included in that group is a TVT-O patient.
Q Have you removed mesh from a patient in whom you've implanted the sling?
A I have.
Q And how many times, approximately?
A My estimate would be ten.
Q In any of those cases, did they involve a transobturator device?
A I cannot recall. I would assume, because most

of my sling procedures utilized one of the TV types of devices, that that would be included in that group.

Q Did you or have you performed a removal procedure in a patient for the treatment of pain?

A No.

Q Have you removed mesh to address dyspareunia?

A No.

Q Have you removed mesh from patients for the treatment of retention?

A Yes.

Q Okay. And of the 30 that you've removed, Dr. Schwartz, what -- if you could give me a general idea of whether the indication for removal was retention, erosion or some other indication.

A The majority were for erosion.

Q In any of those instances where you removed mesh, have you reviewed the explanted material microscopically?

A No.

Q Have you asked a pathologist to review the material that you've removed microscopically?

A I have sent the material to the pathologist for them to assess.

Q Okay. And are you aware of any pathology that has been examined microscopically of those explants that

you've performed?

A I am not aware of any.

Q Would it be the general practice at your hospital only to review explanted mesh under gross examination?

A Yes.

Q And so you've not requested that they do anything other than the normal procedure at your hospital, correct?

A I have done nothing more than request that they assess it like any other pathology specimen I would send.

MS. O'DELL: May we go off the record?

(Off the record at 9:59 a.m.)

(A recess was taken.)

(Back on the record at 10:02 a.m.)

BY MS. O'DELL:

Q Dr. Schwartz, have you had any patients who have reported new-onset dyspareunia after the implantation of the TVT-O?

A Not of patients that I've implanted.

Q Have you treated patients who have developed dyspareunia after the TVT-O?

A I recall one or two patients that did have that as part of their grouping of problems after a sling

procedure.

Q And how did you treat those patients? What was your -- what's your typical method for treating a patient who develops dyspareunia after a transobturator sling?

A It depends on the particular patient and what the clinical scenario is, obviously making sure there is nothing I feel is surgically correctable. And, if they are postmenopausal patients, which many of mine are, if they are not on some form of estrogen, I will prescribe that. And I'll typically work with a gynecologist to see if they have any additional treatment suggestions.

Q Have you performed any surgeries on patients who developed dyspareunia after the TVT-O, such as cutting the sling or removing the mesh, in order to address their dyspareunia?

A I have not had to operate on any patients for the complaint of dyspareunia.

Q Now, you acknowledge, I'm sure, that pain and dyspareunia is reported in the literature as a complication of the TVT-O?

A At a very low occurrence rate, along with a whole host of other complications.

Q And what complications are you referring to when you say a host of complications?

A That are stated, actually, in the paragraph that you read. I think that's a really good example.

Q And this was the paragraph that I read on Page, I believe, 6 of your report?

A Yes.

Q And it's your opinion that those are, the risks that are presented on Page 6, are similar in midurethral slings, whether they are TVT, TVT-O or mini-sling, true?

MR. KOOPMANN: Object to form.

THE WITNESS: To different degrees.

BY MS. O'DELL:

Q Would you agree with me, Dr. Schwartz, that groin pain is reported in the literature as a complication of TVT-O slings?

A Groin pain is reported as a complication of every type of surgical treatment for stress urinary incontinence, yes.

Q Would you agree with me that groin pain is reported at a more than fivefold increase in TVT-O slings versus other types of incontinence procedures?

A I think you would have to be more specific as to "other types of incontinence procedures."

Q So is it your opinion, Dr. Schwartz, that groin pain, leg pain and dyspareunia does not occur in

greater frequency in patients who have a TVT-O or transobturator sling as compared to other surgical treatments for SUI?

A That's a complicated question. Could you repeat it?

MS. O'DELL: I'm going to ask Lynn if she could read it.

(The record was read back.)

MR. KOOPMANN: Object to form.

THE WITNESS: The occurrence of transient groin and hip pain is reportedly increased in patients who have had a transobturator procedure.

BY MS. O'DELL:

Q What do you mean by "transient"?

A Typically resolving within a matter of days to weeks.

Q And what do you rely on in making that statement?

A There is a -- there are many high-quality published studies that have shown that to be the case.

Q Let me show you what I'm marking as Exhibit 7.

(Exhibit 7 marked for identification.)

BY MS. O'DELL:

Q This is an article you are familiar with. The first author named is Schimpf, S-C-H-I-M-P-F, published

in the American Journal of Obstetrics and Gynecology in 2014.

If you'll turn, Doctor, to Page -- it's 71.e9.

Do you see that, Table 3?

A Yes.

Q And in the review that was performed of all of the literature regarding transobturator, retropubic, Burch, mini-sling and pubovaginal slings, this study group created an analysis. And if you'll look under Groin Pain, isn't it true that in obturator slings groin pain occurred in 6.5 percent of the patients, and in every other treatment modality it was 1.5 percent or less, true?

A True.

Q Okay. And if you will look in terms of leg pain, leg pain was reported in 16 percent of patients who received an obturator sling and reported in 1.6 percent or less in retropubic or mini-sling, true?

MR. KOOPMANN: Object to form.

BY MS. O'DELL:

Q True?

A The findings of groin pain and leg pain are increased, but, once again, the majority, if not all of those instances, I believe are reported to be transient.

Q And what do you base -- and you made that

statement -- I've spent a good amount of time with this Schimpf article.

What did you rely on to reach the conclusion that those reported adverse events are transient?

A I'm relying on a host of other studies that have specifically commented on the occurrence of leg and groin pain, as well as outlining the specific amounts of time to resolution and the treatments necessary to address the pain.

Q And there is nothing in this Schimpf systematic review that refers to these complications of groin pain and leg pain as transient, true?

A There is -- there is no description. There is no specific description beyond what we're seeing here in the chart, yes.

Q So you've made an assumption that these outcomes were transient, but there is no data in this publication to support that, true?

A I'm relying on multiple other studies that have specifically addressed that breakdown. This study has not done that.

Q Is it your opinion that one of the benefits of the TVT-O is the lower percentage of patients who have to return to the operating room following a first procedure?

A Benefits compared to what in particular?
Q As compared to another SUI surgical procedure.
A Can you restate the question for me?
Q Happy to.
As you have evaluated the safety and efficacy of the TVT-O, did you consider the reoperation rate?
A With any procedure I do, I would consider the potential reoperation rate.
Q In your opinion, is the reoperation of the TVT-O, the reoperation rate of the TVT-O, one of the characteristics that make it, in your mind, an advantageous procedure?
A The reoperation rate for the sling procedures that I do are all exceptionally low, so I would not rely on that particular factor to make a decision on what procedure to use.
Q Are you basing that statement on your personal experience?
A I'm basing that statement on a combination of my personal experience and the complication rates that are quoted in the literature.
Q Would you agree with me, Dr. Schwartz, that Burch procedures, either open or laparoscopic, have a lower rate of return to the operating room for retention, erosion, overactive bladder and groin pain?

MR. KOOPMANN: Object to the form.

THE WITNESS: The Burch procedure, in my experience, has far more potential problems, potential problems than midurethral sling surgery.

In terms of your question, which is, Do patients have a higher rate of returning to the operating room for Burch procedure, I don't believe they do.

BY MS. O'DELL:

Q Okay. If you'll turn to e11 of the Schimpf publication that we've marked as Exhibit 7 and look at Table 4.

Following the schematic review that was performed by the authors, they concluded that Burch procedures may result in lower rates of return to the operating room for retention, erosion, overactive bladder symptoms and groin pain.

Do you see that?

A I do.

Q Do you disagree with that statement?

A I comment that they are not discussing the overall, all complications of the Burch procedures, just the ones that are listed there.

Q What is your basis for -- well, let me just ask this.

Are you saying that statement is incorrect?

A No, I'm not. I agree with that statement but that statement is, is including return to the operating room for those four distinct issues.

Q And reoperation rate and the return to the OR is a significant adverse event, true?

A True.

Q I mean, the whole idea is, you have the sling implanted and you are not going to have to ever have to go back to the operating room, be placed under general anesthesia and undergo another procedure with all of the inherent risk of a surgical procedure, true?

A Surgery is a combination of science, skill and the art of medicine. And, with any surgical procedure, as you are probably aware, there are going to be instances where return to the operating room is warranted.

My job as a continence surgeon is to provide patients with information regarding complications and how those complications are addressed.

The rate of erosion --

Q Sir, I want to let you finish, but that's really not my question. So let me just refocus the discussion.

A Okay.

Q If a procedure -- let me ask you this.
What is an unacceptable rate of reoperation after a procedure before you would think that procedure is not safe?
A I don't believe that that question can be answered in generalities.
Q If you had a rate of reoperation of greater than 10 percent of a procedure that is intended to be a permanent treatment, would you consider that rate to be too high?
A Once again, I think that's -- I cannot comment on generalities. When I do a complicated cancer surgery, there are rates that are clearly higher than 10 percent. And patients are aware of that, for reoperation for major complications. And that is something that a patient has to decide. It's my job to provide them the information to make a good decision.
Q What rate of reoperation do you give to your patients in whom you are going to implant the TVT-O?
A In my hands, less than 5 percent.
Q Do your patients always return to you for treatment of complications? Do you track patients and their complications?
MR. KOOPMANN: Objection to form.
THE WITNESS: We do track patients, patients

insomuch as if they do not return for their postoperative visits, we contact them, all patients, for all reasons, and will document why the patient hasn't followed up.

BY MS. O'DELL:

Q What is your normal postoperative follow-up schedule?

A For what procedure?

Q For a TVT-O.

A I will -- my typical follow-up schedule, if a patient is having no postoperative problems, is to see them in two weeks.

Q Do you see them again after that?

A Yes, I do. If they are having no issues whatsoever, I will see them again in three months. If they are having issues, I may see them a week later, two weeks later. It all depends on what their concerns are.

Q Is it your opinion that the reoperation rate for the TVT-O is 5 percent?

MR. KOOPMANN: Objection. Form.

MS. O'DELL: What's wrong with the question?

MR. KOOPMANN: Well, I think it could be vague, because I don't know what reoperation rate you are talking about, if it's overall or specific.

MS. O'DELL: He just testified a few minutes

ago that his reoperation rate was 5 percent.

BY MS. O'DELL:

Q Is that what you said?

And my question to you, is that based on your personal experience?

A It's based on my personal experience.

Q But you do not keep a log of your procedures for the TVT-O, true?

A True.

Q And you do not have a systematic follow-up for your patients beyond the follow-up that you just outlined, true?

A I follow up on my patients longer term, if that's what you are asking.

Q Do you call them a year out, Dr. Schwartz, or 18 months out, and ask them if they are doing okay?

A I see -- if my patient is having no issue after their three-month visit, I see them in six months for follow-up. If the patient is having no issues after six months, I see them in one year. If in one year they are doing -- they are having no issues, then I specifically tell them that they are discharged and if they should have any problems to please contact me.

Q Is that your follow-up protocol for every patient who has a surgery for stress incontinence?

A Every patient, yes.
Q Every patient.
Okay. Beyond the one-year mark, is there any attempt to follow them?
A Yes. So if we're talking typically, two weeks, three months, then six months, then one year later, that gets me to, oh, about a year and three quarters.
Q Do you keep a registry of any complaints lodged by your patients in regard to a particular medical device implanted?
A I do not.
Q Would you agree with me that a device that has been reported in the literature to have a reoperation of greater than 15 percent is unsafe?
MR. KOOPMANN: Objection to form.
THE WITNESS: I could not make that comment.
BY MS. O'DELL:
Q In terms of your appreciation of the risk and benefits, would that evaluation -- strike that. I'll start again.
Turn to Page 17 of the Schimpf article, e17, Dr. Schwartz.
You'll see in the middle column, the first paragraph, "Rate of reoperation for SUI at three years

of follow-up favored retropubic in this population. 18.3 percent of women in the obturator group required reoperation versus 1.2 percent in the retropubic group on intention-to-treat analysis."

In your opinion, is an 18.3 percent reoperation rate an acceptable rate of reoperation in terms of safety?

A I'm assuming that they are including patients who are being reoperated on for recurrent or persistent incontinence.

Q My question is, Is an 18.3 percent reoperation rate an acceptable rate for a medical device in terms of safety?

A I don't believe that 18 percent is reflecting the safety issues of the sling.

Q I disagree with you. We're going to disagree a lot today. But assuming it is -- strike that.

Taking a person back to the operating room has significant risk, true?

A No. Not necessarily.

Q It's a serious adverse event to have to go back to the operating room, true?

A That must be qualified with the fact that incontinence procedure has a very clear success rate, subjective and objective, and there are patients who

will decide to return to the operating room if they have a leakage episode after bungee jumping, and there are some patients who are perfectly happy going from six pads to two pads and feel that they have had a wonderful success.

So I don't believe you can characterize return to the operating room in terms of, simply in terms of complications.

Q So you don't think return to the operating room is a serious adverse event?

MR. KOOPMANN: Object to form.

THE WITNESS: Return to the operating room --

BY MS. O'DELL:

Q Yes or no. So if it's a no, that's fine.

A No.

Q Fair enough.

And you believe that that 18 percent is composed of women who experience infrequent episodes of SUIs? Is that your opinion?

A No. That potentially includes patients who have not achieved their desired level of continence.

Q And what do you rely on in making that statement?

A I would have to review the whole paper to give you a specific answer.

Q But you are making an assumption by saying that at this point, true?
A I am. I am making an assumption.
Q When the TVT came on the market, were you an early adopter?
A An early adopter of the TVT?
Q Excuse me. Were you an early adopter of the TVT-O?
A Yes.
Q And were you provided samples of the TVT-O to use in your practice prior to it being marketed?
A I'm not sure I understand the question.
Q Were you provided samples of the TVT-O device right at the time or prior to it becoming available to the general population of surgeons?
A That was provided to me at the time that it became, was -- yes. At the time it became available.
Q At that time was there any clinical data to support the efficacy and safety of the TVT-O?
A Yes. There was clinical data to support that.
Q What was it?
A I would have to review my loose-leaves here to answer that for you.
Q And in your view, is a one-month study of less than 100 or 107 patients sufficient clinical data to

perform a procedure?

A Based on the fact that I was familiar with the mesh and am familiar with pelvic anatomy and felt that that would be beneficial to patients as compared to what was available, yes. I had already been performing outside, in slings, with the Monarc device, so I was very familiar with the procedure, with the anatomy, with potential problems that could arise and how I had to inform patients.

Q Do you agree with the statement that a procedure involving a medical device needs to be subjected to thorough clinical testing before it should be placed on the market?

A Not necessarily.

Q And in your opinion, there was adequate clinical data at the time that you started using the TVT-O?

A Yes.

Q Were you aware that Ethicon made a decision that clinical data would not be required prior to launching the product?

MR. KOOPMANN: Object to form.

BY MS. O'DELL:

Q And by "product" I mean the TVT-O.

A I cannot recall reading anything to that

effect.

Q Do you think it's important that a medical device manufacturer have data prior to placing a device on the market that is going to be implanted in patients permanently?

A That absolutely depends on what types of devices are already available for use, as well as the similarities, the differences. Is it a similar material? Is it the same type of mesh? There are many factors that should go into that answer.

Q Would you agree with me it would be wrong for a company to place a device on the market that utilizes a different method for implanting the device in the absence of clinical data?

A Once again, it would depend on what devices and materials are already available from that company and from other companies.

Q When the TVT-O was placed on the market, were there any other transobturator slings -- there were no other transobturator slings that used the inside-out method, correct?

A Correct.

Q And that was a new method for implanting a midurethral sling, true?

A That was a variation on an already established

method.

Q It was a new way to implant the sling, true?

MR. KOOPMANN: Object to form.

THE WITNESS: Once again, it was the same procedure.

BY MS. O'DELL:

Q Performed differently?

A Performed with a variation, yes.

Q So it's not the same as the Monarc, true?

MR. KOOPMANN: Object to form --

BY MS. O'DELL:

Q -- in terms of the manner in which it was implanted?

A Correct.

Q True?

A Correct.

Q I mean --

A Yes. True.

Q And there was no data on the TVT-O at the time of launch, true?

A There was data on the -- on the TVT-O when it was launched.

Q Okay. Let me ask you this question and move to a new topic. There wasn't, but we'll move on.

Starting on Page 16 of your report, if you

will turn back to that, you go through a series of articles, starting with Dr. de Leval and colleagues.

Did you write this portion of your report?

MR. KOOPMANN: Object to form.

Don't provide information regarding your drafting of the report. That's privileged information, the preparation of the reports.

BY MS. O'DELL:

Q Did you select the studies that you have focused on beginning on Page 16 of your report?

A I was -- I had integral involvement in the studies in the whole report.

Q How were they selected?

A Well, the initial study by de Leval is --

Q No, sir. I'm asking you how you selected these, the studies that you have summarized in your report. I'm asking you --

A Relevance.

Q Okay. Turning to Page 17, Dr. Schwartz, you mention a study by Angioli. On Page 18. Excuse me.

You state that there were no reports of chronic pelvic pain in the Angioli study.

Have you reviewed that study, sir?

A Yes.

Q And was chronic pelvic pain an end point of

that study?

A I would have to review the study.

Q Do you know?

A I cannot answer that without reviewing the study. Would you like me to review it?

Q Well, if you need to review it, we'll go off the record and I'll be happy to have you do that.

MR. KOOPMANN: We need to stay on the record. If you want to ask specific questions about the literature, then that's part of the deposition.

MS. O'DELL: I'm just asking him a specific question.

MR. KOOPMANN: If he's going to review it, I think time spent reviewing articles that you want him to ask him a specific question about --

MS. O'DELL: I disagree with that.

BY MS. O'DELL:

Q If you want to read the study, sir, I'm happy to hand it to you.

A There is a big one with "TVT."

MS. O'DELL: We should go off the record.

MR. KOOPMANN: I think we should stay on the record, or I'm objecting to going off the record to answer questions that you are asking about a specific article.

MS. O'DELL: We should go off the record.
(Discussion off the record at 10:43 a.m.)
(Back on the record at 10:44 a.m.)
MS. O'DELL: Back on.
All right. Lynn, would you please re-ask the question.
(The record was read back.)
THE WITNESS: Not according to the objective.
BY MS. O'DELL:
Q Let me show you what I'm going to mark as Exhibit 8.
(Exhibit 8 marked for identification.)
MS. O'DELL: Sorry, Barry. I don't have another copy.
BY MS. O'DELL:
Q You note in Groutz the cure rates.
And, Dr. Schwartz, in considering Groutz, did you -- why didn't you consider or note that in elderly patients there was a 19 percent increase in -- or occurrence -- excuse me -- of de novo OAB in patients who were elderly?
A Well, it was -- I summarized, and there was one paragraph with several sentences.
Q Did you consider, in evaluating Groutz, that 11 percent of the patients who were younger had thigh

pain that lasted one to three months?

A I'm not sure I understand the question.

Q Do you consider an occurrence, 11 percent occurrence of thigh and leg pain after a procedure to be a significant frequency in terms of an adverse event?

A All adverse events have to be discussed with patients, and if this procedure provided less overall complications, and equal or better outcomes, then prior procedures that I've done -- then I would consider transient leg or thigh pain, which is what I consider this to be, acceptable, and especially when it's discussed with the patient.

Q At what point would you consider leg and thigh pain not to be transient? If you consider three months transient, at what point does it become a chronic condition?

A When, despite various basic treatment options, it doesn't resolve or if it doesn't resolve spontaneously with time. And I qualify that because surgical incisions hurt, and they can most certainly hurt for three months or even six months. But it's clear to me that nearly all of them resolve with time and will resolve spontaneously.

Q What literature do you base your opinion on that three months is considered to be transient? Do you

have a reference that you rely on in making that statement?

A I do not, no. I'm basing that on my own clinical experience.

Q And you would agree with me, wouldn't you, Dr. Schwartz, that there is literature that notes any condition that continues consistently to 9 weeks, it would be considered a chronic condition, true?

A I don't necessarily agree with that.

Q And in outlining your opinions regarding the Groutz article, you failed to note the incidence of OAB, thigh pain, urge and UTIs, true?

A They were not included.

Q You write on Page 20 of your report that "high-quality evidence has shown complication rates with midurethral slings such as the TVT-O to be low."

What percentage of a complication rate do you consider to be low? In other words, what percentage do you have to reach before, in your mind, it tips over to be not a low rate of complications but an unacceptable rate?

A That's completely dependent upon the procedure and what is being defined as "a complication rate." Some people would define persistent incontinence a complication and assign that a complication rate, while,

in actuality, that's not a complication rate.

Q That's a failure, true?

A Correct.

Q And do you find that a de novo overactive bladder at a rate of 24 percent in the first year, the the first year following the implant of an TVT-O, to be an acceptable rate in terms of the safety of a TVT-O sling?

A If a patient considers their outcome to be more beneficial than their occurrence of OAB symptoms, yes.

Q What if they don't? What if they would rather leak than have frequency and urge 24/7?

A Well, my experience is when that is the case that I can address their de novo OAB symptoms fairly easily.

Q You've told us about your experience. Is there any reference in the literature that you've cited that supports that conclusion?

A There are -- there are mounds of literature to discuss the effectiveness of antimuscarinic and anticholinergic medication in addressing OAB symptoms.

Q Is that literature that you've read and relied on and listed in your materials in this case?

A No.

Q Is there any literature that you've relied on in rendering your opinions specifically related to the TVT-O that would support your statement that a 24.3 percent rate of overactive bladder following the implant of a TVT-O is an acceptable complication rate?

A My opinions -- my opinions and stated facts are based on an entire career of accumulation, and there is no way that that can be excluded from comments I have dealing with the TVT-O, nor can I include all of the medical literature regarding all of the facts to get to this level here in this room. It would be onerous and unreasonable.

Q And so I appreciate your comment, but, to be fair, you are basing what you are saying on your personal experience, true?

A I don't agree with that.

Q I mean, I just heard you say that you are basing it on your personal experience in your individual practice, true?

A No, no. The data that looks at the effectiveness of overactive bladder with anticholinergic or antimuscarinic oral therapy shows that it is exceptionally effective in addressing those issues.

Q Well, and, Dr. Schwartz, to be clear, I didn't ask you about the effectiveness of those therapies.

What I asked you was whether it was your opinion that a 24.3 percent rate of de novo OAB following the implantation of a TVT-O was an acceptable complication rate, and you said, "Yes, based on my experience."

Did I understand that correctly?

MR. KOOPMANN: Object to form.

THE WITNESS: No. I commented very specifically that it is an acceptable result if patients find their procedure to be successful.

BY MS. O'DELL:

Q What if they don't find their procedure to be successful; is that an acceptable rate of OAB, de novo OAB?

MR. KOOPMANN: Object to form.

THE WITNESS: I don't necessarily consider that to be excessive or problematic and is certainly treatable nonsurgically.

BY MS. O'DELL:

Q Yes or no.

MR. KOOPMANN: Object to form.

THE WITNESS: Could be. I can't apply a yes or no to that question.

BY MS. O'DELL:

Q Do you tell your patients when you discuss with them a TVT-O that they have a 24 -- one-in-four --

let me put it this way: One in four, approximately, patients will have de novo overactive bladder?

MR. KOOPMANN: Object to form.

THE WITNESS: What I discuss with my patients regarding overactive bladder is that 60, 60 to 70 percent of them who have overactive bladder symptoms will derive significant benefit from their continence surgery, and that, if they do not have those symptoms, that they can develop after the procedure.

BY MS. O'DELL:

Q Do you tell your patients who do not have OAB prior to the implantation of a TVT-O device that they have a one-in-four chance of having OAB following the procedure? Yes or no.

A No.

Q Do you tell your patients -- let me back up and ask it this way.

Is an outcome following the implantation of a TVT-O of one in four women having de novo dyspareunia an acceptable outcome, in your opinion?

A The literature has extensively looked at the rates of dyspareunia following that procedure, and various high-quality, large studies have shown that rate to be exceedingly low.

Q What studies are you referring to?
A There are -- there is the AUA 2009 study that came out in 2012. And there is -- several of the -- there is the large Cochrane analysis.
Q Did you consider, in rendering your opinions, studies that showed a high rate of dyspareunia in cases where a patient was implanted with a transobturator sling?
A I reviewed many, many studies that discussed dyspareunia.
Q That's really not my question.
Did you review studies involving a transobturator device that reported rates of dyspareunia at 24 percent in rendering your opinions in this case?
A I may have.
Q Did you or do you recall that?
A I do not recall -- I cannot recall the specific percentage.
Q Can you recall any studies that you reviewed that showed an increase in dyspareunia in patients who had a transobturator sling of greater than 10 percent?
A I cannot state that specifically.
Q Let me show you what I'm marking as Exhibit 10.
(Exhibit 10 marked for identification.)

BY MS. O'DELL:

Q Have you seen this study before?

A I don't think I have.

Q And so it's fair to say, if you haven't seen it, you didn't consider it in rendering your opinions, true?

A True.

Q And if you'll look in the abstract, Dr. Schwartz, on the right side, it says, "De novo internal dyspareunia was reported in 4 out of 17, or 24 percent, of the transobturator group and none in the retropubic group."

Do you see that?

A Yes, I do.

Q And that was not information you took into account in rendering your opinions, true?

A True. This is a rather small study.

Q Is a study with 127 women a study with an acceptable size?

A Well, it's more than 25 transobturator patients in this study.

Q What methodology do you utilize in determining if a study has sufficient size for you to consider it?

A Part will be the statistical relevance.

Q How many patients, in your mind, is a

sufficient number in order for a study to be worth your consideration?

A Any study is easy to review. I don't know that I'd necessarily not review a study based on the number of patients, but I do consider that a statistical significance, when comparing outcomes, when comparing complications, is important.

(Exhibit 12 marked for identification.)

BY MS. O'DELL:

Q Let me show you what I'm marking as Exhibit Number 12.

Did you consider this study in rendering your opinions in this case?

A I don't recall.

Q And this is a study comparing the TVT to the TVT-O. It involves 127 patients. Do you see that in the abstract under Results?

A Yes.

Q Following that, it says, "The study was stopped early due to excess leg pain and tension-free vaginal tape obturator group." It goes to know to say, "More women complained of leg pain after receiving a tension-free vaginal tape obturator, TVT-O, in 26.4 percent versus 1.4 percent in the retropubic group."

Do you see that?

A I do, and I'm well aware that the transobturator procedure does have an increased risk of leg pain. And I use that with many other factors in deciding what is the safest and most effective procedure for a patient.

Q And so you would agree with me that in patients who develop leg pain following the TVT-O that the TVT-O is a reasonable explanation for the cause of their leg pain?

A The procedure is likely the cause of their leg pain.

Q That's not really what I asked you, but let me ask you this way.

Would you agree with me that the implantation of a TVT-O in the presence of the TVT-O device in a patient is a reasonable explanation for leg pain following the implantation?

A I'm not sure I understood the question.

Q Would you agree with me that the implantation of a TVT-O in the presence of a TVT device in a patient is a reasonable explanation for leg pain following the procedure?

A I'm sorry. It's still an ambiguous question to me.

Q What's ambiguous about it?

A That I've stated that the procedure is likely what contributes to the leg pain.

Q In your opinion does the presence of a mesh through the obturator foramen contribute to the development of leg or groin pain?

A Unlikely. It's the procedure itself. It's the going through the muscles, going through the fascial tissues, having some trauma to those tissues, some degree of hematoma there, all contributes, not to mention being in stirrups with your hips flexed to 90 degrees.

Q Well, the procedure itself is dictated by the instructions for use that's generated by Ethicon, true?

A A technical description of the procedure is in the IFU.

Q That describes a pathway of the mesh through the obturator foramen, true?

A True.

Q And you would criticize a physician who departed from the instructions for use in implanting, the procedure, true?

MR. KOOPMANN: Object to the form.

THE WITNESS: Not necessarily. I mean, every patient, every single patient has slightly different anatomy. Every procedure has to be

typically adapted in some way to address that particular patient.

BY MS. O'DELL:

Q You write in your report that one of the benefits of a TVT-O procedure is that it's reproducible each time.

Is that different than what you are saying now, that a surgeon should feel free to vary the procedure in any way that they deem appropriate?

A Those comments are not mutually exclusive.

MS. O'DELL: Move to strike as nonresponsive.

BY MS. O'DELL:

Q In your opinion, Dr. Schwartz, is groin pain at a rate of 16 percent an acceptable outcome following the implantation of a TVT-O?

A Yes.

Q Sir, what is the exhibit number on the study?

A Twelve.

Q In your opinion, over what time after the implantation of a TVT-O would you expect to see erosion?

A My experience has been that episodes of erosion will be identified prior to six months.

Q Is that opinion you've just stated, is that published in the literature?

A Well, you asked me for my opinion.

Q I did.
A I gave it to you.
Q Okay. And here is my job today. When you give an opinion, whether you express it here in your deposition or in your report, I have the job to ask you what you are relying on in rendering your opinion, and this is my opportunity to learn that. And if there is something you are relying on that's not reflected in these materials or it's specific, I would like to know it, and I think I'm entitled to know that.
So if you say that there is going to be erosion following a TVT-O, that it's going to be six months, then I would like to know what you are relying on. If it's your personal experience only, then you just tell me that.
A And I am not only relying on my personal experience. The vast majority of studies that identify erosion identify them as early complications.
MS. O'DELL: How long have we been going?
THE COURT REPORTER: Two hours and 15.
MS. O'DELL: So we have 45 minutes left.
(Exhibit 13 marked for identification.)
BY MS. O'DELL:
Q Let me show you what I'm marking as Exhibit 13, Dr. Schwartz.

Have you seen this publication?

A I don't believe so.

Q Okay. And this article, first author, Zhang, published in 2016, followed 120 patients that were randomized in either TVT or TVT-O. And you'll see in -- the tape exposure was possible up to seven years after the TVT-O.

Do you see that?

A Yes.

Q And that's not something that you considered in rendering your opinions in this case, true?

A No. That's -- no, that's not true. It's not something that I consider typical, even despite the low rate of erosion.

Q You had not considered this study when you rendered your opinions in this case, true?

A Correct. Correct.

Q And would you consider an objective cure rate of 69.35 percent to be acceptable following the implantation of a TVT-O?

A It depends on the study selection and who was included. In some scenarios that would be perfectly acceptable.

Q For a index patient under the AUA guidelines, is that an acceptable cure rate?

A Because I haven't had the chance to look at this, if these are patients who were undergoing secondary procedures, yes, that's -- if this study includes patients undergoing -- also undergoing secondary procedures, then that would be an acceptable cure rate.

Q If it's initial procedures, which I think that to be the case, but, if it's initial procedures, is a 69.3 percent cure rate acceptable in your mind?

A Not being consistent with most of the literature in terms of acceptable rates, I don't find that to be dramatically different than the typical literature, which has much better results.

Q So you would discount this study and the outcomes or the -- yes, the outcomes of the study?

A I can't discount any study until I have had an opportunity to fully review and scrutinize the specifics.

Q And that's not one that Ethicon counsel made available to you, correct?

A Not that I recall.

MR. KOOPMANN: Object to form.

BY MS. O'DELL:

Q Turning to Page 28 of your report, Dr. Schwartz, you write, "I have used mechanically cut

TVT-O slings and I have used laser-cut TVT-O Abbrevo and TVT-Secur slings, and I have found there to be a" -- excuse me -- "I have not found there to be a clinically significant difference in the way mesh itself performs."

We've already discussed you don't keep a registry nor a log of your surgical procedures, true?

A True.

Q Do you keep a register or log of the patients in whom you implant a mechanical cut mesh versus laser-cut mesh?

A No.

Q Have you done any study or review of your patients to determine if there is a clinically significant difference in how the meshes perform? In other words, have you reviewed their charts? Have you done anything to inform yourself as to whether there is a clinically significant difference between how laser-cut versus mechanical put mesh is performed in your patients?

A I simply rely on my clinical experience.

Q Is that a no?

A I do not -- I have not performed a study identifying who has laser-cut and mechanical cut mesh.

Q You write, In my patients in whom I've implanted mechanically cut TVT-O sling, I have not seen

fraying, roping or curling as plaintiffs' experts have suggested."

Have you examined the mesh that you've removed from patients to determine if it is fraying, curling, roping?

A I've examined it grossly, yes.

Q Have you documented those findings in any way?

A In an operative report?

Q Yes.

A No.

Q Have you made any other notation of your gross examination of explanted mesh?

A No.

Q Do you perform ultrasounds, vaginal ultrasounds of your patients in order to evaluate implanted mesh?

A No.

Q Have you done a literature search to find studies that have evaluated the way mesh changes, frays, ropes or curls in vivo?

A I have read several studies that have discussed mesh issues, and I believe that was included.

Q Have you done any review or search yourself to seek out studies that describe the fraying, roping or curling of the mesh in vivo?

A I have not done a specific literature search on those issues.
Q And so you are relying on the literature that Ethicon counsel has provided to you, correct?
MR. KOOPMANN: Object to form.
THE WITNESS: Yes.
BY MS. O'DELL:
Q Dr. Schwartz, have you ever designed a mesh?
A No.
Q Do you have any training as a medical device engineer?
A No.
Q Do you have any training in materials in terms of the properties of polypropylene or how it reacts to agents within the body?
A Insomuch as I've used polypropylene for 25 years in many different forms.
Q Have you performed any scientific studies?
A No, I have not.
Q Have you performed any experiments on polypropylene to evaluate how it reacts to agents found within the human body?
A No experiment.
Q You go on to say, "The strong efficacy in safety exhibited in public literature on MUS predating

the ability of laser-cut mesh slings is consistent with a strong efficacy and safety exhibited in the published literature since laser-cut mesh has been available."

Did I read that correctly?

A I think so.

Q I tried to. I'm not sure I did, but I've tried to give it my best shot. Here is the question.

Are you aware of any published clinical literature that identifies whether a TVT-O device was laser-cut or mechanical cut?

A Please repeat that.

Q My point is, you say, "The strong efficacy exhibited in the published literature on MUS predating the availability of laser-cut," and you go on to talk about mechanical cut. The bottom line is this. Are you aware of any studies involving patients that include information as to whether the mesh is laser-cut or mechanical cut?

A Well, one can extrapolate if a study included only mechanically cut mesh based on the date because it was before the laser-cut mesh was available.

Q My question is, Are you aware of any clinical trials that specifically delineate whether the TVT-O that was implanted was mechanical cut or laser-cut?

A Are you asking me have there been studies

comparing the two?

Q I'm asking you, in the published literature, is there any study involving a TVT-O that identifies the specifics as to whether the mesh was laser-cut or mechanical cut? Yes or no.

A Not that I know of.

Q You say, "Nor have I seen any clinically significant contraction in the TVT-O mesh slings that I have used. In my experience tissue ingrowth occurs as expected following the implantation of the sling, and while the scar tissue can be expected to contract to an extent, I have not seen a contraction of the tissue that leads to problems."

What have you done to evaluate whether mesh contracts?

A Clinical examination.

Q What do you mean by that?

A Examining patients after their procedures have been performed to assess for any palpable mesh, any erosions, any other local issues.

Q And you are talking about performing a pelvic exam and attempting to palpate the mesh, true?

A I'm talking about after patients have their procedure, examining them to confirm whether I can identify any problems.

Q Do you, in those pelvic exams, make any effort to measure the change in the mesh in terms of surface area from the time of implant to the time that you evaluate it?

A I can tell you that I can almost never feel the mesh after implantation.

Q That's not my question.

Do you make any effort to measure the difference in the surface area from the date of implant to the date of your examination?

A But that's an impossible question.

Q Yes or no. Do you or do you not?

A No.

Q Have you reviewed literature that evaluates contracture of mesh?

A I have reviewed some studies that discuss in vivo mesh changes.

Q Would you agree with me, if the surface area of mesh is reduced by 36 percent, that could result in a patient experiencing pain?

A I don't believe it's the surface area of the mesh that's reduced. I believe it to be the ingrowth of fibroblast and other tissues and part of wound healing that result in the change that you are mentioning.

Q And what do you base that opinion on?

A I base that opinion on my knowledge of Prolene and my clinical experience.

Q If experts that Ethicon sought out disagreed with your opinion, would you defer to those experts?

A It would depend on their opinion.

Q Let me show you what I'm marking as Exhibit Number 14.

(Exhibit 14 marked for identification.)

BY MS. O'DELL:

Q Dr. Schwartz, have you seen this document before?

A I don't believe so.

Q I'll represent to you that this is a document that memorializes the discussion that took place on June the 2nd, 2006. It was a meeting posted by Ethicon, and it had participants that were Ethicon employees, as well as academic physicians and experts that Ethicon invited to come together to discuss mesh properties.

And if you'll turn to Page 2 and you look at the bottom of the page, you'll see two line items that deal with shrinkage.

Do you see that?

A Yes.

Q And the discussion is that shrinkage of 20 percent means a reduction of mesh area, surface area, to

64 percent. In other words a 36 percent reduction in the surface area of the mesh.

Is that information that Ethicon ever provided to you?

MR. KOOPMANN: Object to form.

THE WITNESS: Not that I recall.

BY MS. O'DELL:

Q And would you agree with me that a 36 percent reduction in the surface area of mesh more likely than not will have clinical significance?

A I disagree.

Q Okay. And in disagreeing with that, is there any literature that you are relying on in making that statement?

A I'm relying on the multitude of high quality literature that attests to the effectiveness of the procedure and, as such, the mesh up to 15-plus years. So I maintain that the clinical relevance is directly related to those results.

Q And you are talking about the Nilsson series of studies that focus on efficacy. Is that what you are referring to?

MR. KOOPMANN: Object to form.

THE WITNESS: One of them.

BY MS. O'DELL:

Q Any others?
A There are. I would have to --
Q Would you --
A -- go through.
Q Excuse me. Sorry.
Would you agree with the general principle that contraction of 36 percent of the surface area of mesh increases the risk of pain?
A No.
Q And did you evaluate any studies that focus on the clinical significance of mesh contracture in patients who have been implanted with a midurethral sling?
A I recall a study that looked at explanted mesh.
Q Do you recall the name of it?
A I do not.
Q And do you remember the first author?
A I do not.
Q And do you recall the outcome of the study generally? I'm not talking about specifics, but what brought it to your mind. Obviously, you are thinking of something.
A Yes. No. I recall that the, that that was a fairly unique report that looked at a subset of patients

who had mesh explanted.

Q And what was the conclusion, as you recall?

A I didn't find the conclusion very clinically useful.

Q What was it?

A That they were talking -- discussing different characteristics that were found after further examining explanted mesh.

Q And what was their conclusion?

A I can't exactly recall the conclusions.

Q Was the conclusion that contracture of the mesh contributed to adverse events associated with the mesh product?

A I can't recall if that was the case, but I would disagree with that anyway.

Q Okay. What's your method for disagreeing with it? How did you discount that?

A Based on a combination of the medical literature and my experience, the contraction that occurs with fibroblast ingrowth certainly occurs but does not result in clinical significance. And that's supported by the high degree of effectiveness, even longer term, with this material.

Q Well, in terms of contracture, its implication is not on effectiveness, is it, Doctor, but rather on

the safety of the product, true?

A Can you repeat that for me?

Q In terms of contracture, the implication is not on the effectiveness of the mesh but rather on the safety, true?

A I don't know that I agree with that.

Q Okay. Let me ask you one other question, just to make sure I've rounded that out.

Have you ever performed any studies, independent of your own -- strike that.

Have you ever performed any studies to measure contracture in transvaginal mesh?

A No.

Q Have you ever published on it?

A No.

Q You go on to say on Page 29 that "Plaintiff's experts have offered the opinion that the mesh and the TVT family of products is cytotoxic and degrades. I disagree."

What do you mean by "cytotoxic"?

A Destructive to human tissue.

Q Are you referring to chronic inflammation when you say "cytotoxicity"?

A No.

Q And in terms of -- did you say destruction of

human tissue? Is that your definition of cytotoxicity?

A Yes. Cells and human tissue.

Q And on what basis do you conclude that mesh is not, to use your word, cytotoxic?

A Once again, based on my experience with implant, explant, examining patients and the millions and millions of women who have had successful mesh implants provides me with a large amount of information that mitigates against the mesh being cytotoxic.

Q Have you reviewed mesh -- are you a pathologist?

A Sorry?

Q Are you a pathologist?

A No.

Q Are you a materials expert?

MR. KOOPMANN: Object to form.

THE WITNESS: Just insofar as I have used certain materials for decades.

BY MS. O'DELL:

Q But you don't study them in the same way that a materials science or a polymer scientist would, true?

A True.

Q And you have put them in for decades, but you've never gone into a laboratory for purposes of evaluating microscopically a mesh product, true?

A True.
Q And in the women who have come to you for treatment and you have removed mesh, have you examined that mesh for purposes of determining if it has degraded?
A Just gross inspection only.
Q And so if degradation is not possible to appreciate grossly, then you have never reviewed mesh for purposes of determining that it has degraded, true?
A I have never microscopically examined explanted mesh.
Q And on what basis do you say, Dr. Schwartz, that TVT-O mesh does not degrade?
A Once again, based on my clinical experience implanting and explanting the mesh and the long-term studies that look at the effectiveness. If the mesh degraded, the procedure efficacy would be dramatically different. And when I explant mesh, it looks very similar to when I implant the mesh, but I'm talking grossly.
Q You are stating that the mesh, when you explant it, looks similar to pristine mesh when you remove it?
A No. It has fibroblast ingrowth and --
Q It looks remarkably different, true? In fact,

you can barely see the mesh due to, you know, tissue, blood, et cetera?

MR. KOOPMANN: Object to form.

THE WITNESS: I can always see the mesh.

BY MS. O'DELL:

Q The mesh fiber is covered in tissue and I'm assuming blood from the procedure in many instances, true?

A True. But I can always identify the blue mesh. I believe I've only implanted blue-colored mesh.

Q Well, fair enough. You can see the color blue, but in terms of examining the mesh fibers, the mesh is covered in material that would prevent you, on gross examination, from determining if there has been degradation or breakdown in the actual fiber, true?

A I can only assess it grossly. I have not assessed it microscopically.

Q So is that true?

A You would have to repeat the question.

Q Yes.

Okay. And has Ethicon ever shared with you the information they have about the fact that Prolene degrades in vivo?

MR. KOOPMANN: Object to form.

THE WITNESS: Not that I know of.

BY MS. O'DELL:

Q Have you reviewed -- let me say this, to save time.

If Ethicon internally has known that Prolene degrades in vivo since 1987, that would be news to you, correct?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes. I'm not aware of that information.

BY MS. O'DELL:

Q Would you want to see that information in order to consider your opinions in this case that mesh does not degrade?

A I don't think that that would affect my choice of procedures.

Q That's not my question.

You have opined specifically that mesh does not degrade. If Ethicon has information that categorically states that Prolene degrades, is that information you would want to have in rendering your opinions in this case?

A The clinical significance of mesh degradation, if it occurs to any significant degree, has no signs, that I have found, affecting outcome of the procedures.

Q All right. Is it no longer your opinion that

mesh does not degrade?

MR. KOOPMANN: Object to form.

BY MS. O'DELL:

Q Because what I hear you saying now is it may degrade, but, if it degrades, it's not clinically significant. So here is the question.

Does it degrade? Is it your opinion it does not degrade?

A In my experience --

Q No, sir.

A But in my experience there is no clinically significant mesh degradation.

Q Now. Okay. So, as I read your report, it says, "Plaintiff's experts have offered the opinion that the mesh in the TVT family of products is cytotoxic and degrades. I disagree."

It should be you are not disagreeing that it degrades, you are just saying it's not clinically significant in your view; is that your opinion?

A From my -- from my research all I can say is, from a materials science standpoint, I have not read any material that convinces me that there is any significant degree of mesh degradation.

Q Let me just -- is it your opinion that mesh does not degrade?

A It is. It is my opinion that there is, based on my experience with Prolene, I don't believe that there is any significant degree of mesh degradation.

Q So when it says, "I disagree," in regard to degradation, you are changing your opinion to say, I don't think it's significant, I don't think it degrades significantly?

A I'm not changing my opinion.

Q You are not changing it.

So when you say you disagree, what are you relying on?

MR. KOOPMANN: Object to form.

THE WITNESS: I'm relying on, once again, my clinical experience with Prolene, with the mesh and the long-term efficacy studies. That's what I'm basing my opinion on.

BY MS. O'DELL:

Q And so in your mind efficacy is a matter of -- degradation is a matter of efficacy and not safety, fair?

A I feel that safety would certainly be an issue as well. I've -- I -- my research has not suggested that there are safety issues arising from a causal relationship with mesh changes.

Q Let me show you Exhibit 14.

(Exhibit 14B marked for identification.)

BY MS. O'DELL:

Q Have you seen this document before?

A I have not.

Q You'll see it's dated September 30th, 1987, and the title is IR Microscopy of Prolene, Received from Professor R. Guidoin. I don't know how to pronounce that.

Do you see that?

A I do.

Q If you'll turn to Page 2, sir.

Under Conclusion, No. 3, it says, "The IR spectra of this scraped material is clearly polypropylene but it appears to be degraded in an oxidative fashion."

Do you see that?

A I do.

Q No. 4, "The degraded portion of the 8-year explant makes up only a minor portion of the suture." But clearly there is a finding of degradation.

Do you see that?

A Yes, I do.

Q And that's not information that was provided to you by Ethicon, true?

A I have not seen this report.

Q And have you considered literature -- in what literature have you considered and relied on in regard to your opinion that mesh does not degrade?

A Once again, it's a result of my long-term experience with Prolene and the long-term efficacy studies.

Q Okay. If you'll turn over to Page 30, you say at the top of the page, "Plaintiffs' experts have also offered the opinion that larger pore or lighter weight meshes would have been safer to use in the TVT-O sling. I disagree."

We've established you have not designed a mesh product. Have you published in the area of pore size or mesh density?

A No.

Q Have you performed any research in that area?

A No.

MR. KOOPMANN: Object to form.

BY MS. O'DELL:

Q Have you taught any students about the issue of pore size in mesh density and what those should be in a medical device?

A I discussed this issue with --

Q Have you taught a course on it?

A No, I have not.

Q Do you know the size of the -- strike that.
What's the pore size of the mesh?
A About 1300 microns.
Q What is the density?
A The weight is about 100 grams per meter squared.
Q How do you know that?
A From my research.
Q Your research in rendering your opinions in this case?
A Yes.
Q You say that the pore size and weight are optimal. Is there a specific material that you rely on in order to say that it's optimal?
A My research, basically reading of the material, has suggested that that is an optimal pore size.
Q Have you done an independent research review -- excuse me -- research to determine what has been written regarding pore size and density, outside the materials given to you by Ethicon?
A No, I have not.
Q Sir, what is the last exhibit number that I used?
A Fourteen.

Q Okay.

(Exhibit 15 marked for identification.)

BY MS. O'DELL:

Q Let me show you what I'm marking as Exhibit 15. This is an IFU for the TVT.

I'm assuming you are familiar with this?

MR. KOOPMANN: Leigh, I think you gave me your copy.

BY MS. O'DELL:

Q If you'll turn, sir, to Page -- I believe it's Page 6 or 5 of the exhibit.

Earlier, sir, you testified that, in your mind, transient leg pain was up to three months. Do you recall that?

A Yes.

Q And would you agree with me, under the Warnings and Precautions section, that the transient leg pain that Ethicon defines is 24 to 48 hours?

A I'm sorry. Repeat the question, please.

Q Are you -- what page are you on, sir?

A Six.

Q Okay. Great.

If you'll look down in the Warnings and Precautions section, as it proceeds on to Page 6 of Exhibit 15, you'll see the third bullet point says,

"Transient leg pain lasting 24 to 48 hours may occur and usually can be managed with mild analgesics."

A Yes. I see that.

Q And is it fair to say your opinion of transient leg pain being three months is very different from what is described here in the IFU, true?

MR. KOOPMANN: Object to form.

THE WITNESS: Leg pain is leg pain.

BY MS. O'DELL:

Q Okay. Ethicon in the IFU defines "transient" as 24 to 48 hours. Do you see that?

MR. KOOPMANN: Object to form.

THE WITNESS: It's not clear to me that they define it that way.

BY MS. O'DELL:

Q They don't say three months, do they, sir?

A They say "may occur."

Q Twenty-four to 48 hours of leg pain is a very different complication following a procedure than consistent leg pain of three months. Would you agree with that?

A I comment that the majority of my patients have leg pain lasting up to 48 hours. There are -- I have had patients with some degree of leg pain that does not resolve for up to three months.

Q And that would -- according to the IFU, that would not be transient leg pain, true?

MR. KOOPMANN: Object to form.

THE WITNESS: I define transient leg pain as I've defined it, which is pain that resolves on its own.

BY MS. O'DELL:

Q That's your definition of transient leg pain?

A Transient leg pain, yes, is that it resolves spontaneously.

Q Are you suggesting -- let me just cut to the chase.

Does the IFU warn of chronic leg pain?

A The IFU can't include every single --

Q That's not my question.

A I understand that.

Q So here is my question.

Does the IFU include chronic leg pain?

A They list transient leg pain, is how they define it.

Q Does it include a warning of leg pain that lasts beyond 48 hours?

A Not specifically.

Q And you would agree with me, Dr. Schwartz, that studies such as the Teo study that we looked at

earlier, Exhibit 12 reports leg pain of much longer than 48 hours in upwards of 26 percent of the patients in that particular study.

Do you recall that?

A I recall looking at that study, yes.

Q And so it would be fair to say there was information available of instances of leg pain that lasted longer than 48 hours that were not included in the IFU, true?

A There is no way that the IFU can include all potential issues that can arise from surgery.

Q And so is the answer to my question yes, that's true?

MR. KOOPMANN: Object to form.

THE WITNESS: I'm sorry. You'll have to repeat the question.

BY MS. O'DELL:

Q The IFU does not warn of leg pain lasting longer than 48 hours, does it, sir?

A The IFU makes no specific reference to leg pain lasting longer than that time.

Q And the IFU does not warn of dyspareunia, true?

A I do not see dyspareunia listed here.

Q And it does not include a warning of urge

incontinence, urgency or frequency, true?

A Well, by the same token it doesn't comment that it will prompt improvement in the majority of women who have that problem.

Q We're talking about warnings and adverse reactions. And let me ask you to turn to Page 32 of your report.

You say, "There is no need for Ethicon to warn surgeons about risks inherent in any pelvic floor surgery," and you include infection, inflammation, bleeding, scarring, bladder damage, bowel damage, nerve damage, urethral damage, pain, pelvic pain, dyspareunia, groin pain, and you go on to list others.

Is it fair to say that, regardless of what the known risks are, those adverse outcomes, they were not included in the IFU of the TVT-O?

A Once again, I don't feel that's the role of the IFU.

Q Have you ever written a warning for a medical device or an IFU?

A No, I have not.

Q Have you been asked to consult with a medical device manufacturer to assist in writing an IFU?

A I have not been asked to assist in writing an IFU.

Q And is it your opinion that you outline here on Page 32 what was not necessary to include in the IFU, based on your personal experience?
A And the experience of my colleagues as well.
Q What colleagues are you referring to?
A My surgical colleagues.
Q Your partners?
A Yes.
Q In your medical practice?
A Yes.
Q Anything else?
A Basically surgeons in general. Surgeons don't rely on IFUs to provide them with complication information.
Q And what do you base that statement on?
A That most --
Q Sir, I'm asking for a reference.
A Most procedures don't have an IFU available.
Q I'm talking about a medical device, and all medical devices have IFUs, and I'm asking, when you say there is no need to put into an IFU known risks of a procedure, you've stated that you base that on your personal experience and talking with your colleagues.
Is there anything else you base that opinion on?

A Not that I can think of currently.
Q In your view, Ethicon has no duty to provide information about risk of a product; is that fair?
MR. KOOPMANN: Object to form.
THE WITNESS: Is that stated here?
BY MS. O'DELL:
Q I'm asking you the question, sir.
A I'm sorry. What was the question?
Q The question is, In your view, does Ethicon have a duty to provide information about known risks of a product in an IFU?
A No. The surgeon is responsible for understanding and learning about risks of procedures from literature, peer-reviewed textbooks, peers, meetings, et cetera.
Q Does Ethicon have a duty to provide information about known risks to patients in their patient brochures?
MR. KOOPMANN: Object to form.
THE WITNESS: That's a duty that should fall on the surgeon.
BY MS. O'DELL:
Q So if Ethicon is printing a brochure for distribution to patients who are going to ostensibly be implanted with a TVT-O or another device in the TVT

family, do they have a duty to include known risks?

MR. KOOPMANN: Object to form.

THE WITNESS: No. That's the job of the surgeon.

BY MS. O'DELL:

Q Are you going to opine, to a reasonable degree of medical certainty, that Ethicon provided adequate training to surgeons on the implantation of the TVT-O?

A Ethicon provided me with adequate training and I in turn provided other surgeons with adequate training.

Q Do you have any opinion as to the overall training provided by Ethicon to surgeons who purchase the TVT-O product?

A I cannot attest to what their experience was.

Q You can only attest to your own experience?

A Correct.

Q Okay.

MS. O'DELL: I've got about five minutes left, and I'll reserve it.

MR. KOOPMANN: So I should ask my follow-up questions now?

MS. O'DELL: If you have any.

CROSS EXAMINATION

BY MR. KOOPMANN:

Q Dr. Schwartz, counsel asked you some questions about the Schimpf article earlier.

Do you still have that one in front of you? It's here.

If you'll turn to Table 3.

A Yes.

Q In that article you will see the adverse event rates for various types of adverse events for various types of sling procedures and non-sling incontinence procedures, correct?

A Correct.

Q And one of the rates referenced there is a dyspareunia rate with obturator procedures of 0.16 percent; is that right?

A Correct.

Q And is this article an article that you relied on in forming your opinions in these cases?

A Yes.

Q The rate of return to operating room for erosion was 2.7 percent in the transobturator sling patients, correct?

MS. O'DELL: Object to form.

THE WITNESS: Correct.

BY MR. KOOPMANN:

Q And what was the rate of exposure for

transobturator sling patients?

A 2.2 percent.

Q What was the rate of wound infection for transobturator patients?

A 0.74 percent.

Q And what was the rate for pubovaginal sling patients?

A 2.6 percent.

Q And what was the rate of wound infection for Burch procedure patients?

A 7 percent.

Q What was the rate of bowel injuries for obturator patients?

A Nonexistent.

Q What was the rate of bowel injury for Burch patients?

A 3.13 percent.

Q Is bowel injury a significant adverse event?

A It's a potentially life-threatening event.

Q What was the rate of overactive bladder or urgency in obturator patients, based on this study?

A 0.3 percent.

Q And this study is a systematic review and meta-analysis?

A Yes.

Q Is that high quality scientific evidence?
MS. O'DELL: Object to form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q What was the rate of overactive bladder or urgency in the pubovaginal sling patients?
A 8.6 percent.
Q And what was it in the Burch patients?
A 4.3 percent.
Q What was the rate of retention lasting longer than six weeks in the obturator patients?
A 2.4 percent.
Q And was that rate -- how did that rate compare to the other rates studied?
A It was the lowest of the group, including obturator, retropubic, mini-sling, pubovaginal and Burch.
Q And one of the articles that counsel asked you about was the Cholhan article.
A Yes.
Q If you'll turn to the second page of that article, on the right-hand side they talk about, "More than half of their patients, 28 out of 52, underwent concurrent surgery for prolapse in addition to the transobturator or retropubic sling."

Do you see that?

A I see that now.

Q And then they go on to note after that, that, "Of the four transobturator patients with de novo internal dyspareunia, two had supracervical hysterectomy with abdominal sacrocolpopexy and one had a posterior colporrhaphy, and one had a transobturator sling alone."

Is that right?

A Correct.

Q You were also asked some questions about the Teo study. Do you recall that?

A Yes.

Q Okay. And in the Teo study, if you'll turn to the second to last page, there is a discussion of leg and groin pain being experienced by 26.4 percent of the women of the TVT-O group, which is what counsel asked you about, right?

A Yes.

Q Further down, in the middle of that paragraph, it says, "There was sufficient response to amitriptyline and gabapentin, which obviated the need for tape removal in those patients."

Is that right?

A Yes.

Q And then it says, "In all other cases of leg

pain in the TVT-O group the problem resolved spontaneously within three months."

Is that right?

A Correct.

Q Another article you were asked about is the Zhang study.

A Yes.

Q And they note in the Zhang study, in the Results section of the long-term complication rates for TVT and TVT-O were 43.1 percent and 27.4 percent respectively; is that right?

A Yes.

Q And counsel asked you about tape exposure being possible seven years after the TVT-O. Do you remember that?

A Yes.

Q Okay. If you'll turn to the second to last page you'll see the Conclusions section.

A Yes.

Q And at the end of that Conclusions section, the authors of this Zhang study noted that, "Despite the high incidence of long-term complications most complications were not consequential and the patient's QOL retained significant improvements in the long term."

Is that right?

A Correct.

MS. O'DELL: Object to the form.

BY MR. KOOPMANN:

Q What is "QOL"?

A Quality of life.

Q And they also note that sexual function was unchanged by either procedure; is that right?

A Correct.

Q You were asked some questions a few minutes ago about the instructions for use for the TVT obturator.

In the Adverse Reaction section on Page 6 of that document it notes that, "Punctures or lacerations of vessels nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair."

Is that right?

A Yes.

Q And as a urologic surgeon and pelvic floor surgeon, is it obvious to you that pain could result from punctures or lacerations of vessels, nerves, bladder, urethra or bowel?

MS. O'DELL: Object to form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q And did you need an IFU to tell you that pain

could result from adverse reactions like that?

A No.

Q As a urologic surgeon, do you know that pain could result after any surgery?

A Pain can result following any surgery.

Q Can it result after a Burch procedure?

MS. O'DELL: Object to form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q Can it result after pubovaginal sling procedures?

A Yes.

Q And can pain that results after any surgery be temporary or permanent?

A Yes.

Q Handing you some of the articles that you've got in file materials here today, and ask you some questions about some of those.

A Okay.

MS. O'DELL: Do you have a copy for me?

MR. KOOPMANN: I do.

BY MR. KOOPMANN:

Q One of the articles you have there is the Abdel-fattah study. Do you see that one?

A Yes.

Q In that study the authors looked at a database with 34,631 women; is that right?
A Yes.
Q And this is a study that you reviewed in the course of forming your opinions in this case?
A Yes.
Q If you will look at Page 5 of the study, it indicates in the left-hand column that, "Sixty-seven women had at least one repeat urinary incontinence surgery, giving a reoperation rate of 8.8 percent."
Is that right?
MS. O'DELL: Can you show me where you are reading, please?
MR. KOOPMANN: Right here.
THE WITNESS: Left side, second paragraph.
MR. KOOPMANN: Yes. Halfway through the paragraph. Page 5.
MS. O'DELL: I gotcha.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q And then on the right-hand column at the top it says, "The reoperation rate for urinary incontinence was 3.2 percent in the midurethral sling group, 10.7 in the abdominal retropubic surgery group."
Is that right?

A Yes.

MS. O'DELL: Object to the form.

BY MR. KOOPMANN:

Q You also have a study there by Ford and others, the Cochrane review.

Do you have that?

A Yes.

Q This is a study that you reviewed and relied on in forming your opinions in these cases?

A Yes.

Q And on the third page there they noted -- third page of the document, but it's labeled Page 2 at the bottom?

A Okay.

Q It says Main Results at the top?

A Yes.

Q And in the fourth paragraph in that page it notes that, "The overall rates of vaginal tape erosion/exposure/extrusion was low in both groups: 24 out of 1,000 instances with the transobturator compared with 21 out of 1,000 for the retropubic."

Is that what that indicates?

A Yes.

Q And do you have, as part of that document -- it's the last page, Page 30 and 31. That's the last two

pages.

A Yes.

MR. KOOPMANN: Do you have those, Leigh?

MS. O'DELL: Yes.

BY MR. KOOPMANN:

Q And at the bottom of Page 30 the author has assessed sexual function, quality of life measures.

Do you see that section?

A Yes.

Q And the bottom paragraph in that column, it says, "In all the trials there was significant improvement in sexual function from baseline scores during the follow-up period that spans 6 to 24 months."

Did I read that correctly?

A Yes.

Q And it says, "There were no significant differences between the two groups at 24-month follow-up. Rates of superficial and deep dyspareunia were low with no difference between the groups."

Is that right?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q And if you go back to Page 2 that we looked at a moment ago, this study looked at 55 trials with data

contributed by 8,652 women, which compared the use of the transobturator route and retropubic route.

Is that right?

A Yes.

Q Do you have an article there by Michele Jonsson Funk?

MS. O'DELL: Are you going to mark these for the record?

MR. KOOPMANN: Well, they are part of his file materials. Are you going to mark his file materials?

MS. O'DELL: I've marked all I'm going to mark, but if you don't mark them, I'll mark them when I go back on the record. Otherwise it's not going to make any sense. I suggest you mark them, but it's up to you.

MR. KOOPMANN: I didn't know if you had marked these, that particular stack.

All right. I'll mark them.

(Exhibit 17 marked for identification.)

BY MR. KOOPMANN:

Q I'll mark for the record as Exhibit 17 a copy of the Ford record article that was just discussed and is in your file materials; is that correct?

A Correct.

Q And then I'll mark as Exhibit 18 a copy of the --

MS. O'DELL: Abdel-fattah?

THE WITNESS: I have copies, two copies in my pile. I just have to find it here.

(Exhibit 18 marked for identification.)

BY MR. KOOPMANN:

Q And then you've got a copy of the Jonsson Funk article from your file. Let's mark that as Exhibit 19.

(Exhibit 19 marked for identification.)

BY MR. KOOPMANN:

Q You haven't commented on that. I'll ask you some questions about this.

I've marked it as Exhibit 19; is that correct?

A Yes.

Q And this study looked at 188,454 eligible women who underwent an index sling procedure?

A Yes.

Q And they found that, "The nine-year cumulative risks of sling revision/removal was 3.7 percent."

Is that right?

A Yes.

Q You had mentioned earlier the 2009 AUA guidelines regarding the surgical management of stress incontinence --

A Yes.
Q -- that was updated in 2012.
Do you have a copy of that in your file?
A Yes.
Q We'll mark that.
(Exhibit 20 marked for identification.)
MS. O'DELL: Is it Exhibit 20?
MR. KOOPMANN: Yes.
BY MR. KOOPMANN:
Q And if you'll turn to the second to last page, you should see Appendix A16.
Do you see that page?
A Yes.
Q Okay. And these are guidelines that you reviewed and relied on in forming your opinions in this case?
A Yes.
Q And in that Appendix A16, it lists complication rates for synthetic slings at the midurethra; is that right?
A Yes.
Q And it notes a rate of pain as a subjective complication at a rate of 1 percent; is that correct?
MS. O'DELL: Object to form.
Excuse me, Doctor.

Are you on Page A16, Synthetic -- are you on the last page or the next to last page of this exhibit?

MR. KOOPMANN: It is the second to last page.

MS. O'DELL: Okay. All right. Do you mind repeating your question?

MR. KOOPMANN: In the middle column, it says Synthetic at Mid-Urethra.

Do you see that section?

MS. O'DELL: Yes.

BY MR. KOOPMANN:

Q Dr. Schwartz, the subjective complication of pain was reported to occur in 1 percent of patients studied, correct?

A Yes.

MS. O'DELL: Object to the form.

BY MR. KOOPMANN:

Q Was what I said correct?

A What you said was correct.

Q And what was the rate of sexual dysfunction?

A Zero.

Q What was the rate of voiding dysfunction?

A 2 percent.

Q Do you have a study by Giovanni Tommaselli in your stack of materials there?

A Yes.

(Exhibit 21 marked for identification.)

BY MR. KOOPMANN:

Q Before I move on from the AUA guidelines, I've marked those as Exhibit 20; is that correct?

A Correct.

Q Would you please put that Exhibit 21 sticker on the Tommaselli article?

A (The witness complies.)

Q This article by Dr. Tommaselli and colleagues was written in 2015; is that correct?

A Yes. Accepted for publication 2015.

Q And this was a systematic review and meta-analysis, correct?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q And if you'll turn to Page -- well, it's the page with Table 3 on it.

Do you see that page?

A Yes.

Q That shows the number of total transobturator sling patients that were studied in the article, correct?

A Yes.

Q And the total was what?
A The total transobturator, 1,500 -- no. All studies, 2,432.
Q Okay. And then if you'll turn to the next page, you'll see the paragraph that's got a header Tape-Related Long-Term Complications.
Do you see that?
A Yes.
Q And what does it say there in the second sentence in that paragraph?
A Starting "persistent"?
Q Yes.
A "Persistent or severe voiding problems" --
Q I think you've got the wrong one. Second sentence, not the third.
A "Persistent or chronic pain, pain persisting beyond the peri-operative period or reported at the last follow-up visit, was reported by 13 patients for the retropubic MUS and 30 patients for the transobturator MUS."
Q And if you do that calculation, 30 patients divided by 2,432, it would be a 1.2 percent rate of chronic or persistent pain with the transobturator procedure, based on this study?
MS. O'DELL: Object to the form.

THE WITNESS: Yes.
BY MR. KOOPMANN:
Q And that's a study you reviewed and relied upon in forming your opinions in this case?
A Yes.
Q You have a study there by Cecile Unger and colleagues?
A Yes.
Q I'll mark that as Deposition Exhibit 22.
(Exhibit 22 marked for identification.)
BY MR. KOOPMANN:
Q Is this a study that you reviewed in the course of forming your opinions, relied on?
A Yes.
Q And this study involved an analysis of 3,307 women who underwent sling placement; is that right?
A Yes.
Q And 89 of those women, or 2.7 percent of the 3,307, underwent sling revisions for one or more of various indications; is that right?
MS. O'DELL: Object to the form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q And of that 2.7 percent that underwent a sling revision, 21.3 percent of those were for mesh erosion;

is that right?
A Yes.
Q So 21.3 percent of 2.7 percent?
A Yes. That's about 5 1/2 percent.
MS. O'DELL: Object to the form.
BY MR. KOOPMANN:
Q So 21.3 percent of 89 people, it would be 19 people; is that right?
MS. O'DELL: Object to the form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q And 19 people divided by 3,307 women would yield a complication rate of 0.57 percent; is that right?
A Yes.
Q And then vaginal pain and dyspareunia was the indication for sling revisions in 7.9 percent of the 89 women; is that right?
A Yes.
Q Okay. And 7.9 percent of 89 is seven people, if you trust my math?
A Yes.
MS. O'DELL: Object to the form.
BY MR. KOOPMANN:
Q And seven women out of 3,307 would be 0.21

percent?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q And then 3.4 percent of the 89 women had sling revision for groin pain; is that right?

A Correct.

Q Do you have a study in front of you there by a Dr. Welk and colleagues?

A Yes.

MR. KOOPMANN: Let's mark that as Deposition Exhibit 23.

(Exhibit 23 marked for identification.)

BY MR. KOOPMANN:

Q Is this a study that you reviewed and relied upon in forming your opinions in this case?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q This study looked at -- well, it was a population-based retrospective cohort study that included all adult women undergoing an incident procedure for SUI for synthetic mesh in Ontario, Canada, from April 1st, 2002, through December 31st, 2012.

Is that right?

A Yes.
Q And in the Results section it indicates there that, "Among the identified 59,887 women" -- strike that.
It indicates that there were 59,887 women studied as part of this group, this article, correct?
A Yes.
Q And they note in the middle of the Results section there that, "Complications were treated in 1,307 women or 2.2 percent."
Is that right?
A Yes.
Q And they note that the ten-year cumulative incidence rate was 3.29; is that right?
A Yes.
Q And then in the Conclusion Section they note that, "Ten years after SUI mesh surgery 1 of every 30 women may require a second procedure for mesh removal or revision."
Is that correct?
A Yes.
Q And that's a study that forms the basis or part of the basis for your opinions in this case?
MS. O'DELL: Object to the form.
THE WITNESS: Yes.

BY MR. KOOPMANN:

Q You were asked some questions earlier about the Angioli study. Do you remember going through that?

MS. O'DELL: I didn't mark the study.

MR. KOOPMANN: You didn't?

THE WITNESS: It's here. Do you want me to --

BY MR. KOOPMANN:

Q You have it included in your TVT-O general report binder notebook that you brought?

A Yes.

Q Let's mark that notebook as Exhibit 24.

(Exhibit 24 marked for identification.)

BY MR. KOOPMANN:

Q Counsel asked you some questions about what the primary end point was for this study.

Do you recall that?

A Yes.

Q And the Measurements section, what does it say was the primary end point of this study, Measurement Section of the abstract -- let me start that over.

A Okay.

Q In the Measurements section of the abstract, what do the authors indicate was the primary end point of the study?

A Long-term complications.

Q And this was a five-year study of the tension-free vaginal tape versus transobturator suburethral tape?
A Yes.
Q Specifically the TVT versus TVT-O slings, correct?
A Yes.
Q And the authors' conclusions were that both surgical techniques, meaning the TVT and TVT-O, were safe with similar results and low complication rates; is that correct?
MS. O'DELL: Object to the form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q On Page 673 of that study, in the right-hand column there is a reference to dyspareunia. And it says, "Dyspareunia and incontinence during intercourse occurred in 2, or 5.1 percent, and 4, or 10.2 percent, respectively, of the 39 sexually active women who completed follow-up."
Is that right?
A Yes.
Q In Table 4 they report long-term complications that they saw in the TVT and TVT-O patients; is that right?

A Yes.
Q How many cases of urinary retention did they see in the TVT-O patients?
A Zero.
Q How many cases of de novo urgency?
A Two.
Q How many cases of chronic pelvic pain in the TVT-O patients?
A Zero.
Q How many cases of pain during intercourse in the TVT-O patients?
A One.
Q How many cases of incontinence during intercourse in the TVT-O patients?
A Two.
Q How many cases of vaginal erosions?
A Two.
Q And in the Discussion section, the right-hand column on that same page, they indicate in the bottom paragraph, "Our data confirmed that neither approach constituted an invasive procedure so that the majority of women, 51 patients, which was 85 percent, would undergo the same procedure again if SUI recurred, especially within the TVT-O group."
Is that correct?

A Yes.

MS. O'DELL: Object to the form.

BY MR. KOOPMANN:

Q Is that consistent with what you've seen in your patient population with your TVT-Os?

A Correct.

Q Are your patients generally happy with the outcome of the procedure?

A Yes.

Q Turn to Page 675 of the Angioli study. In the left-hand column, second full paragraph starting with "development of"?

A Uh-huh.

Q There is a sentence there that says, "TVT-O seems to be associated with a better impact on sexuality, but there are insufficient data to allow the comparison between retropubic and the transobturator procedures with respect to sexual activity after surgery."

Is that right?

A Yes.

Q And then on Page 676 of that article they noted that out of the three vaginal erosions, that they saw only one of the three was symptomatic while the other two were found during a routine gynecologic exam;

is that right?
A Yes.
Q Do you have a study there from Dr. Serati in your notebook in 2013?
A Yes.
Q And that's contained in the notebook we've marked as Exhibit 24; is that right?
A Yes.
Q And that Serati study, this was a study with five-year follow-up; is that right?
A Yes.
Q And they found that the five-year subjective and objective cure rates with the TVT-O were 90.3 percent and 90.8 percent respectively, correct?
A Yes.
Q In the Discussion section at the top of page 876, the authors noted in the second sentence of that section that they found the TVT-O to be a highly effective and safe procedure; is that right?
MS. O'DELL: Object to the form.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q Do you have a study in your notebook marked as Exhibit 24 by Dr. Liapis?
A Yes.

Q Okay.
A There is an '08 and a '10.
Q The 2010 I have a question about.
This was an efficacy study of the inside-out transobturator vaginal tape, TVT-O, at four years' follow-up; is that right?
A Yes.
Q And in the Results section of the abstract there they say, "The objective cure rate based on the pad test finding for the TVT-O only patients was 82.4 percent and the improvement rate was 6.8 percent."
Is that right?
A Yes.
Q And then they found that the objective cure rate for the group undergoing TVT-O and anterior colporrhaphy was 84.5 percent and the improvement rate was 7.4."
A Yes.
Q In the Introduction section at the bottom of that first paragraph they say, "The aim of this study was to assess the efficacy and safety of the TVT-O procedure with or without cystocele repair in the treatment of USI in women at four years follow-up."
Is that right?
A Yes.

Q The top of Page 201 they note, top of the left column, "Rejection of tape was found in one case on patients with the TVT-O procedure at three months postoperatively and in one case in patients with TVT-O and anterior colporrhaphy at five months postoperatively."

Is that correct?

A Yes.

Q And is this one of the studies that you relied on in forming your opinion that most instances of erosion occur early on after the procedure?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q The bottom of that left column on Page 201 they talk about postoperative pain in the last sentence.

Do you see that?

A Yes.

Q The authors have noted, "Postoperative pain developed in 12.1 percent of patients with TVT-O and 9.7 percent of patients with TVT-O and anterior colporrhaphy."

Is that right?

A Yes.

Q They then noted, "This pain was located in the

thigh region, unilateral or bilateral, and lasted, in the great majority of cases, from one to two weeks but one woman complained of pain for up to four months."

Did I read that correctly?

A Agree.

MS. O'DELL: For optimal completeness I request that you read the next three sentences as well.

BY MR. KOOPMANN:

Q They go to note, "The pain was managed with non-steroidal anti-inflammatory analgesics effectively."

Is that correct?

A Yes.

MS. O'DELL: Keep going.

MR. KOOPMANN: I'll let you cover that, Counsel, if you would like to.

Oh, I see.

MS. O'DELL: "An incidence of up to 16 percent of postoperative pain has been reported and it usually resolves within four weeks but in rare cases persistent groin pain can be seen for up to one year postoperatively."

BY MR. KOOPMANN:

Q Does it state that as well?

A Yes.

Q And the last paragraph of that page says, "In the present study, TVT-O procedure alone or with anterior colporrhaphy maintains a high cure and improvement rate with very low complication rate at four years follow-up and appears to be a promising technique, but long-term results should be published for safer conclusions to be made about its efficacy and tolerability."

Is that what it says?

A Yes.

Q And this is a study that you relied on in forming your opinions in this case?

A Yes.

Q Did you also review and rely on a study by a Dr. Athanasiou, spelled A-T-H-A-N-A-S-I-O-U?

A Yes, from 2014.

Q Yes. And you have that included in Exhibit 24?

A Yes.

Q And this is a seven-year TVT-O study; is that right?

A Yes.

Q Is that a long-term study?

A Yes.

Q This study looked retrospectively at women who

underwent the TVT-O procedure?

A Yes.

Q And they identified in the Results section that, "Overall objective and subjective cure rates were 81.5 percent and 83.5 percent, respectively."

Is that right?

A Yes.

Q And their conclusion was that "the TVT-O procedure provides high objective and subjective long-term efficacy, a clinically meaningful improvement in patient quality of life and an excellent safety profile." Is that right?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q Turn to Page 221, please, of that study.

Actually, go back to 220 for a moment. In the left-hand column, eight lines down, there is a sentence that says, "Current evidence suggests that mid-urethral sling, such as the retropubic tension-free vaginal tape and the transvaginal, tension-free vaginal tape obturator, or transobturator tape, TVT-O, TOT, have become the treatment of choice and are considered the gold standard."

Did I read that correctly?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q Is that a statement that you agree with, that the TVT and TVT-O are the gold standard?

A Yes.

Q Now if you'll go to Page 221. It indicates there that, in the right-hand column about two-thirds of the way down, there is a paragraph that says, "There were no major perioperative complications, such as bladder perforations, vessel injuries and obturator hematomas. One patient, 0.8 percent, reported postoperative voiding difficulties that required tape division three months after surgery."

Did I read that correctly?

A Yes.

Q It also says, "Another patient, 0.8 percent, reported the presence of vaginal erosion diagnosed one year after the procedure. It was situated on the midurethral midline, and a large part of the tape was excised. At the follow-up visit, no cases of vaginal erosions were detected."

Is that correct?

A Yes.

Q They then go on to note, "Assessment of

postoperative urgency symptoms revealed that 76.3 percent of patients with preoperative urgency symptoms reported an improvement at the time of the visit."

Did I read that correctly?

A Yes.

Q And is that one of the articles that supports your opinion that patients with preoperative urgency or overactive bladder symptoms improve after a TVT sling placement?

A Yes.

MS. O'DELL: Object to the form.

BY MR. KOOPMANN:

Q On Page 223 in this study, in the right-hand column, the authors note that, "Groin pain may occur after transobturator procedures but mostly settles within the first month following surgery."

Is that correct?

A Yes.

Q They then note, "Persistent groin pain can be present in up to 3.8 percent of patients."

Is that correct?

A Yes.

Q And then they note, "At follow-up, no patient reported persistent groin pain."

Is that right?

A Yes.
Q Have you been reviewing the literature regarding the TVT-O sling long before you started serving as an expert witness in this litigation?
A Yes.
Q You have been keeping up with the literature regarding incontinence surgeries your entire career; is that true?
MS. O'DELL: Object to the form. Leading.
THE WITNESS: Yes.
BY MR. KOOPMANN:
Q And your review of medical literature, both specifically for purposes of this case and throughout your career as a urologist and surgeon, has formed part of the basis for your opinions that you've set forth in your TVT-O general report; is that correct?
MS. O'DELL: Object to the form.
THE WITNESS: Correct.
BY MR. KOOPMANN:
Q And has your experience in treating patients with the TVT-O sling also formed part of the basis for your opinions regarding the safety and efficacy of the TVT-O sling?
A Yes.
Q And has your review of the medical literature

and your experience regarding the treatment of patients with the TVT obturator sling also formed the basis for your opinions regarding the adequacy of the warnings contained in the instructions for use for the TVT obturator device?

MS. O'DELL: Object to the form.

THE WITNESS: Correct.

BY MR. KOOPMANN:

Q Do you practice evidence-based medicine?

A Yes.

Q What does that mean?

A That means I do everything possible to rely on the literature to make decisions.

Q And is some literature of greater significance than other types of literature?

MS. O'DELL: Object to the form.

THE WITNESS: There is dramatic diversity in terms of quality of medical literature.

BY MR. KOOPMANN:

Q And is there sort of a hierarchy of the levels of different scientific evidence?

A Yes. With Cochrane reviews and the meta-analyses being at the top of that list.

Q Are the complications that you've seen in your practice after treating patients with the TVT obturator

sling consistent with the warnings that you see in the Adverse Reaction section of the Instructions for Use?

MS. O'DELL: Object to the form.

THE WITNESS: Yes.

BY MR. KOOPMANN:

Q Your report that's contained in Exhibit 24 for the TVT-O device, do you hold the opinions set forth in that report to a reasonable degree of medical and scientific certainty?

A Yes, I do.

Q Can you think of a single randomized control trial or systematic review and meta-analysis that you've read that talks about the TVT mesh and the TVT sling degrading or being cytotoxic?

MS. O'DELL: Object to the form.

THE WITNESS: No.

MR. KOOPMANN: I think those are all of the questions I have.

REDIRECT EXAMINATION

BY MS. O'DELL:

Q Dr. Schwartz, you were asked about the Abdel-fattah publication that was marked as Exhibit 18. I think it's in the bottom of that stack, if I recognize it correctly. Okay.

This study, which is an epidemiological study

of the Aberdeen Maternity and Neonatal Database, a Scottish database, evidently, is there any distinction that's made between TVT and TVT-O or are all slings lumped together?

A I don't believe they separate it out.

Q And is that also true of a study that your counsel marked as Exhibit 19, the Jonsson Funk study on sling revision/removal for erosion and urinary retention, long-term risk and predictors?

You can look at mine, sir.

A Thank you. I'm sorry?

Q Is there any distinction that is drawn between retropubic and transobturator slings or are all midurethral slings considered together?

A I don't believe there was a distinction made here.

Q That's right.

And we would agree that the risk-benefit analysis of a retropubic and transobturator sling is different because of the different pathways for the implantation of the sling, true?

A True.

Q And if you'll look at the AUA guidelines your counsel asked about, and they were marked as Exhibit 20 and you were asked to look at the next to the last page

appendix, A16?

A Yes.

Q And synthetic midurethral slings are not divided in this recitation of these numbers, are they? They are considered in composite?

A Correct.

Q And, sir, you were asked some questions about the Cochrane collaboration, Exhibit 17. For the record, it's 2015 Cochrane review.

I would ask you to turn to 28, Page 28.

Do you see that, under Pain?

A Yes.

Q "There was a significantly higher occurrence of groin pain in women who underwent a TOR, or transobturator procedure, than in women who underwent an RPR procedure."

True? Did I read that correctly?

A Yes.

Q You were also asked questions about the Welk study, sir, the Canadian database review?

A Yes.

Q And that epidemiological study does not separate out results between transobturator and retropubic sling, true?

A Correct.

Q Similarly, counsel for Ethicon showed you the Unger study and marked it as Exhibit 22.

A Yes.

Q In this study the authors do not distinguish between implantation of a transobturator and retropubic device, true?

A Correct.

Q You were asked about the Zhang article. I had marked that previously --

A Yes.

Q -- as Exhibit --

A Thirteen.

Q -- 13.

And if you'll turn to the last page of this study, it's right before Conclusions. Do you see on the left-hand side about the middle of the way down the page, there is a sentence beginning "Our data"?

Do you see that?

A Middle of the way down the page?

Q Yes. It says, "Our data demonstrated that 14.49 percent of patients experienced a worsened dyspareunia post-operatively."

Did I read that correctly?

A Yes.

Q And then, lastly, Dr. Schwartz, counsel for

Ethicon marked as Exhibit 21 the Tommaselli publication from 2015.

And if you'll turn to Page -- I believe it's Page 7 under Figure 2. It's the same page you were referred to earlier. I think you are on it.

On the left-hand side, do you see where it says, "Complications were more common with a transobturator midurethral sling than with newer minimally invasive tapes"?

Do you see that?

A Yes.

Q "This result was due exclusively to pain-related complications which were common with transobturator midurethral slings."

Did I read that correctly, sir?

A Yes.

Q Would you agree with me, Dr. Schwartz, that, in light of the literature you relied on, that perhaps increased rates of pain complications with transobturator slings, that for patients who develop de novo pain following the implant of a TVT-O sling, that one of the contributing causes of their pain is the sling itself?

A I would not agree with that.

Q How do you rule out the data that we have just

reviewed from studies that you rely on in reaching that conclusion?

A The postoperative pain symptoms are from the procedure itself.

Q And what basis do you have for stating that it's only the procedure that contributes to pain, it is not the device itself?

A Because that variability is what accounts for most patients not having that pain, the pain being very transient, and --

(Cell phone interruption.)

THE WITNESS: I lost my train of thought. I'm sorry. Can you read me the answer?

(The record was read back.)

THE WITNESS: Can you read me the question?

(The record was read back.)

THE WITNESS: -- that -- a combination of factors, that most patients do not experience any discomfort, the fact -- also the fact that, when it does occur, it typically resolves very quickly, requires very little treatment, if any.

If it was the mesh that was accounting for it, I'm convinced that it would not be transient and it would be in a much higher percentage or potentially all patients.

BY MS. O'DELL:

Q What literature are you relying on to say that, sir?

A I'm relying on what I believe to be the case, based on my clinical experience.

Q Dr. Schwartz, the notebook that's in front of you, are those the articles that you relied on in rendering the opinions in your report?

A Select ones, yes.

MS. O'DELL: I don't have anything further.

MR. KOOPMANN: Okay.

RECROSS EXAMINATION

BY MR. KOOPMANN:

Q Dr. Schwartz, you've brought a lot of materials here today with you; is that right?

A Yes.

Q Okay. And the materials you've brought with you here today are all things that you've reviewed in forming your opinions and relied on in forming your opinions in this case?

MS. O'DELL: Object to the form.

BY MR. KOOPMANN:

Q And counsel hasn't marked all of those as exhibits; is that right?

A Yes.

Q Okay?

MS. O'DELL: I've got about two minutes left. I'll mark them, if that's an issue.

I'm going to mark as exhibit -- what was the last one you left off?

(Exhibit 25 marked for identification.)

MS. O'DELL: I'm marking that binder as 25.

FURTHER REDIRECT EXAMINATION

BY MS. O'DELL:

Q What's that, Dr. Schwartz?

A Which one is this?

Q Twenty-five. I've just marked it and handed it to you.

A What's it called?

Q What is contained in it?

A The TVT-O literature and document set. It's mostly IFUs and patient brochures.

Q Okay. And let me ask you to identify what I've marked as Exhibit 26.

(Exhibit 26 marked for identification.)

BY MS. O'DELL:

Q What's the title of that notebook, sir?

A This is TVT Literature and Document Set.

Q Okay. And if you'll be so kind as to hand it back to me?

Is this binder I've marked as Exhibit 26 the TVT literature and document starter set?

A Yes.

Q And this was provided to you by Ethicon counsel?

A Yes.

MS. O'DELL: I don't have anything further.

FURTHER RECROSS EXAMINATION

BY MR. KOOPMANN:

Q Okay. Doctor, there is an additional document that was part of your file that counsel didn't mark.

Can you tell me what that document is labeled as?

A The Device Labeling Guide.

Q Okay.

A From the FDA.

MR. KOOPMANN: Would you mark that as Exhibit 27? We'll mark that as Deposition Exhibit 27.

(Exhibit 27 marked for identification.)

FURTHER REDIRECT EXAMINATION

BY MS. O'DELL:

Q Have you ever, sir, read that outside -- read Exhibit 27 outside of the context of litigation?

A No.

Q Have you read it inside the context of

litigation?

A I have reviewed it.

Q Is that a fancy way of saying you may have skimmed it?

A Yes.

Q Okay.

MS. O'DELL: I have nothing further.

FURTHER RECROSS EXAMINATION

BY MR. KOOPMANN:

Q Did you read the Warnings section and Adverse Reaction section of Exhibit 27?

A Yes.

Q Is that one piece of information that you've considered in forming your opinions about the adequacy of the warnings in the TVT-O IFU?

A Yes.

MS. O'DELL: Object to the form.

MR. KOOPMANN: Those are all of the questions I have.

MS. O'DELL: Nothing further.

(Deposition concluded at 1:17 p.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF COLLIER)

I, Elizabeth M. Brooks, Notary Public, State of Florida, do hereby certify that, BRIAN SCHWARTZ, M.D., personally appeared before me on the 25th day of March, 2016, and was duly sworn.

Signed this 29th day of March, 2016.

_____

Elizabeth M. Brooks
Notary Public
State of Florida
My Commission No. FF 014169
Expires: June 27, 2017

CERTIFICATE OF REPORTER

STATE OF FLORIDA

COUNTY OF COLLIER

I, Elizabeth M. Brooks, Registered Professional Reporter, Florida Professional Reporter, do hereby certify that I was authorized to and did stenographically report the deposition of BRIAN SCHWARTZ, M.D.; that a review of the transcript was not requested, and that the foregoing transcript is a true record of my stenographic notes.

I FURTHER CERTIFY that I am not a relative, employee or attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 29th day of March, 2016, at Naples, Collier County, Florida.

_____

Elizabeth M. Brooks

Registered Professional Reporter

Florida Professional Reporter